

1 **MCCAULLEY LAW GROUP LLC**
JOSHUA V. VAN HOVEN (CSB No. 262815)
2 E-Mail: josh@mccaulleylawgroup.com
3001 Bishop Dr., Suite 300
3 San Ramon, California 94583
Telephone: 925.302.5941

4 **RICHARD T. MCCAULLEY** (*pro hac vice*)
5 E-Mail: richard@mccaulleylawgroup.com
180 N. Wabash Avenue, Suite 601
6 Chicago, Illinois 60601
Telephone: 312.330.8105

7 *Attorneys for Plaintiff and Counter-Defendant,*
8 **SURGICAL INSTRUMENT SERVICE COMPANY, INC.**

9 **UNITED STATES DISTRICT COURT**
10 **NORTHERN DISTRICT OF CALIFORNIA**

11 **SURGICAL INSTRUMENT SERVICE**
12 **COMPANY, INC.**

13 *Plaintiff/Counter-Defendant,*

14 v.

15 **INTUITIVE SURGICAL, INC.**

16 *Defendant/Counterclaimant.*

CASE NO. 3:21-CV-03496-AMO

Honorable Araceli Martínez-Olguín

**PLAINTIFF SIS's MOTION IN
LIMINE #5**

TABLE OF CONTENTS

RELIEF REQUESTED..... 1

FACTS 1

ARGUMENT.....4

 Legal Standards - Motions in Limine 4

 Admissibility of Relevant Evidence Under Federal Rules of Evidence 401, 402,
 and 403..... 4

 Evidence Attempting to Prove that the FDA Required Usage Limits for
 EndoWrists, or that Adherence to Such Use Limits Are Required or Related to
 Patient Safety Should Be Excluded Under Fed. R. Evid. 402 and 403 5

 Curative Instruction 6

CONCLUSION 6

TABLE OF AUTHORITIES

Federal Statutes

21 U.S.C. § 360(k)	1
Food, Drug, and Cosmetic Act	2
Lanham Act.....	2

Federal Rules

Federal Rule of Evidence 401	4
Federal Rule of Evidence 402.....	4, 5
Federal Rule of Evidence 403.....	4

Federal Regulations

21 C.F.R. § 807.81(a).....	1
----------------------------	---

United States Supreme Court Cases

<i>Luce v. United States</i> , 469 U.S. 38 (1984).....	4
<i>Medtronic, Inc. v. Lohr</i> , 518 U.S. 470 (1996).....	1, 5

Cases

<i>Campbell v. Boston Sci. Corp.</i> , 882 F.3d 70 (4 th Cir. 2018)	5
<i>Federal Trade Commission v. Qualcomm Inc.</i> , 969 F.3d 974 (9th Cir. 2020)	2
<i>Kaiser v. Johnson & Johnson</i> , 947 F.3d 996 (7th Cir. 2020)	5
<i>United States v. Heller</i> , 551 F.3d 1108 (9th Cir. 2009)	4
<i>United States v. Lewis</i> , 493 F. Supp. 3d 858 (C.D. Cal. 2020)	4
<i>Altair Instruments, Inc. v. Telebrands Corp.</i> , 2021 WL 5238787 (C.D. Cal. Feb. 18, 2021)	4
<i>Carter v. Johnson & Johnson</i> , No. 2:20-cv-01232, 2022 U.S. Dist. LEXIS 178596, 2022 WL 4700549 (D. Nev. Sept. 29, 2022)	5
<i>Enberg v. Ethicon, Inc.</i> , No. 2:20-cv-02477, 2022 U.S. Dist. LEXIS 51601; 2022 WL 850762 (E.D. Cal. Mar. 21, 2022)	5
<i>United States v. Holmes</i> , 2021 WL 2044470 (N.D. Cal. November 6, 2021)	4

RELIEF REQUESTED

Plaintiff, Surgical Instrument Service Company, Inc. (“SIS”) hereby moves in limine to exclude all testimony¹, documentary evidence, and argument related to (1) the FDA’s regulatory framework and procedures for clearance of medical devices for commercial marketing, (2) Intuitive’s FDA 510(k) clearance of EndoWrists, (3) the contention that Intuitive’s FDA 510(k) clearance of EndoWrists requires adherence to Intuitive use limits; (4) the contention that Intuitive’s FDA 510(k) clearance of EndoWrists is evidence that those use limits ensure or relate to patient safety; and (5) the contention that Intuitive’s FDA 510(k) clearance of EndoWrists is evidence of the actual number of times an EndoWrist can be used from an engineering/failure perspective.

FACTS

This Court previously addressed the FDA’s 510(k) process in adjudicating the parties’ cross-motions for summary judgment:

Manufacturers or remanufacturers of Class II devices need only submit a “premarket notification” to the FDA in accordance with the less burdensome “510(k) process” rather than the more rigorous process of obtaining “premarket approval” from the FDA necessary for manufacturers of Class III devices. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477-79 (1996) (contrasting the two procedures); *see also* 21 C.F.R. § 807.81(a). “Section 510(k)” refers to the section of the original MDA containing this provision, and it sets forth the procedure by which a medical device that is “substantially equivalent” to a device that is already on the market can be cleared for sale without undergoing the more rigorous pre-market review and approval process. *See* 21 U.S.C. § 360(k); *see also Medtronic*, 518 U.S. at 478-79.

Dkt. 204 at 4:28-5:9. The Court considered communications between the FDA and third parties Restore, Rebotix, and Iconocare regarding their EndoWrist services (*id.* at 5:11-7:13),

¹ For purposes of this motion, “testimony” includes lay person and expert testimony presented at trial either live or through video recordings of deposition testimony.

1 ultimately acknowledging that the “FDA has expressly disclaimed concluding that a violation
2 exists, and it has taken no final position on the need for 510(k) clearance here.” *Id.* at 12:22-
3 23. “The Court, as other before it, declines Intuitive’s invitation to step into the FDA’s shoes
4 and determine whether SIS’s services require 510(k) clearance.” *Id.* at 13:4-5. Accordingly,
5 the Court granted summary judgment in SIS’s favor on Intuitive’s Lanham Act claims and
6 unclean hands defenses related to FDA 510(k) clearance. *Id.* at 11:14-14:28; *see also* Dkt. 240,
7 Exhibit A, Order Clarifying the Scope of the Court’s Summary Judgment Order.

8 Intuitive sought summary judgment on SIS’s claims based on two arguments. The first
9 argument posited that SIS lacked antitrust injury because it lacked 510(k) clearance for its
10 services. This was rejected for the same reasons that SIS’s motion was granted: “[T]his Court
11 will not permit Intuitive to seek private enforcement of the FDCA, an issue upon which
12 Intuitive’s argument against injury causation rests.” Dkt. 204 at 16:23-24.

13 Intuitive’s second argument was that SIS could not prevail on its antitrust claims based
14 on purportedly undisputed evidence of Intuitive’s “procompetitive rationales” for its actions.
15 Dkt. 204 at 17:10-18. According to Intuitive, “it had a reasonable basis for concluding that
16 EndoWrist use limits were necessary, a conclusion affirmed by the FDA in its initial approval
17 of the instruments.” *Id.* at 18:11-13. Relevant to this Motion, the Court held that “[t]o the extent
18 Intuitive argues that its anticompetitive behavior arose from a good-faith attempt to ensure . .
19 . compliance with FDA regulations, it has failed to provide a nonpretextual ‘procompetitive
20 rationale.’ *See [FTC] v. Qualcomm[, Inc.]*, 969 F.3d [974,] 991 (9th Cir. 2020).” *Id.* at 18:17–
21 20.

22 Despite these rulings, Intuitive apparently still intends to inject issues of EndoWrist
23 510(k) approval, remanufacturing, and other FDA clearances into the upcoming trial. For
24 example, **in its exhibit list** Intuitive seeks to introduce at least thirty-three EndoWrist 510(k)
25 documents (Van Hoven Ex. 1 at DX1771.01-DX1771.33), at least eight pre-market approval
26 documents for the da Vinci surgical robot (*Id.* at DX1770.01-DX1771.08), numerous other
27 Intuitive FDA and 510(k) documents (*Id.* at DX1378, DX1410, DX1412, DX1424, DX1452),
28 as well as the same and similar communications between the FDA and Rebotix, Restore, or

Iconocare, that the Court considered during summary judgment. *E.g., id.* at DX0256, DX0257, DX0268, DX1305, DX1308, DX1473, DX1489, DX1516, DX1679.

In its **witness list**, three of ten “Intuitive Fact Witnesses” plan to testify about “regulatory issues,” “regulatory affairs,” or “communications with regulators” and three third parties are proposed to testify regarding “[c]ompetition in the alleged market for the repair and replacement of EndoWrist instruments and regulatory issues.” Van Hoven Ex. 2 at pp. 2-4.

Intuitive’s FDA expert, Christy Foreman, intends to testify that “Intuitive’s marketing and sale of EndoWrist instruments with usage limits is consistent with FDA’s regulatory requirements” and that “Intuitive’s cybersecurity measures are consistent with FDA expectations for devices that are vulnerable to cybersecurity threats.” Van Hoven Ex. 3 at p.8.

Intuitive’s engineering expert, Dr. Robert D. Howe, intends to opine that “the risk management and life data submitted to the FDA for the Iconocare Process is significantly more robust than the risk management and life testing data Rebotix had access to in connection with the Rebotix Process.” Van Hoven Ex. 4 at p. 10, ¶ 35. Intuitive’s intended use of these FDA documents and witnesses at trial is clear from **its proposed jury instructions**. Specifically, Intuitive apparently intends to use a stamp of FDA approval, or lack thereof, to short-circuit legitimate proofs of other contested issues in this case:

- “The Food and Drug Administration (FDA) has granted clearance to Intuitive to market and sell the da Vinci and EndoWrist instruments as safe and effective.” Van Hoven Ex. 5 at p. 3.
- “Intuitive contends . . . the use of EndoWrist instruments beyond the number of lives . . . cleared by the FDA presents serious risks to health and safety of patients; Intuitive has no way to ensure the safety and effectiveness of unauthorized third-party products and services that have not been cleared by the FDA[.]” *Id.* at p. 34.
- “All computer-controlled surgical instrument systems and the instruments used with them, including those that are remanufactured, are required to be approved or cleared by the FDA.” *Id.* at p. 71.

ARGUMENT

Legal Standards - Motions in Limine

“A motion in limine is a procedural mechanism to limit in advance testimony or evidence in a particular area.” *United States v. Heller*, 551 F.3d 1108, 1111 (9th Cir. 2009). Motions in limine are vehicles by which a court may exclude inadmissible or prejudicial evidence before it is “actually offered.” *See Luce v. United States*, 469 U.S. 38, 40 n.2 (1984). Motions in limine “avoid the futile attempt of unringing the bell when jurors have seen or heard inadmissible evidence, even when stricken from the record”; “streamline trials, by settling evidentiary disputes in advance and by minimizing side-bar conferences and other disruptions at trial”; and “permit more thorough briefing and argument on evidentiary issues than would be likely during trial.” *Altair Instruments, Inc. v. Telebrands Corp.*, 2021 WL 5238787, at *1 (C.D. Cal. Feb. 18, 2021) (cleaned up). “[M]otions in limine must identify the evidence at issue and state with specificity why such evidence is inadmissible.” *United States v. Lewis*, 493 F. Supp. 3d 858, 861 (C.D. Cal. 2020) (cleaned up) (citation omitted).

Admissibility of Relevant Evidence Under Federal Rules of Evidence 401, 402, and 403

Federal Rule of Evidence 402 provides that “[r]elevant evidence is admissible” unless the U.S. Constitution, a federal statute, the Federal Rules of Evidence, or “other rules prescribed by the Supreme Court” provide otherwise. Fed. R. Evid. 402. Evidence is “relevant” if: (1) “it has any tendency to make a fact more or less probable than it would be without the evidence”; and (2) “the fact is of consequence in determining the action.” Fed. R. Evid. 401. “Irrelevant evidence is not admissible.” Fed. R. Evid. 402. Federal Rule of Evidence 403 permits a court to exclude relevant evidence “if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.” Fed. R. Evid. 403. Unfair prejudice ‘speaks to the capacity of some concededly relevant evidence to lure the factfinder into declaring guilt on a ground different from proof specific to the offense charged.’ “ *United States v. Holmes*, 2021 WL 2044470 at *5 (N.D. Cal. November 6, 2021).

Evidence Attempting to Prove that the FDA Required Usage Limits for EndoWrists, or that Adherence to Such Use Limits Are Required or Related to Patient Safety Should Be Excluded Under Fed. R. Evid. 402 and 403

“[T]he 510(k) process is focused on equivalence, not safety.” *Medtronic*, 518 U.S. at 493 (internal quotation omitted). Yet, as evidenced by Intuitive’s jury instructions and proposed presentation to the jury discussed above, Intuitive’s main purpose in presenting its own EndoWrist 510(k) approvals and related evidence is the improper purpose of demonstrating that its use limits are required for safety and that exceeding those limits is unsafe. Courts regularly reject medical device companies’ attempts to short-circuit analyses of actual product safety data through presentation of FDA 510(k) approvals and related documents, recognizing that such approvals are of minimal relevance to product and patient safety. *See, e.g., Enberg v. Ethicon, Inc.*, No. 2:20-cv-02477, 2022 U.S. Dist. LEXIS 51601 at *22; 2022 WL 850762 (E.D. Cal. Mar. 21, 2022) (“[C]ourts have found (again and again) that 510(k) clearance does not amount to a safety regulation requiring device producers to meet any established design standards.” (quotation omitted)); *Carter v. Johnson & Johnson*, No. 2:20-cv-01232, 2022 U.S. Dist. LEXIS 178596 at *7, 2022 WL 4700549 (D. Nev. Sept. 29, 2022) (“section 510(k) clearance ‘does not amount to a safety regulation requiring device producers to meet any established design standards’”).

Even if Intuitive now attempts to backtrack and create some other reason to bring these documents and testimony into evidence, the minimal probative value of this evidence is substantially outweighed by the risks of juror confusion and undue deference to a federal agency. *E.g., Carter*, 2022 U.S. Dist. LEXIS 178596 at *7-8 (“many hours, and possibly days, of complex testimony about regulatory compliance . . . could lead jurors to erroneously conclude that regulatory compliance proved product safety”); *Kaiser v. Johnson & Johnson*, 947 F.3d 996, 1018 (7th Cir. 2020) (“It was reasonable to conclude that the probative value of this evidence was minimal at best and that admitting it would precipitate a confusing sideshow over the details of the § 510(k) process.”); *Campbell v. Boston Sci. Corp.*, 882 F.3d 70, 77 (4th Cir. 2018) (“Admitting the evidence on these grounds would invite a battle of the experts

1 regarding the exact meaning of 510(k) approval in these circumstances, and would risk the
2 same jury confusion we feared in [a prior case.]”).

3 Curative Instruction

4 There may be instances – for example, Intuitive’s agreements with hospitals – in which
5 statements regarding 510(k) clearance or remanufacturing are included with other evidence
6 properly presented to the jury. SIS respectfully requests a curative instruction as presented in
7 Van Hoven Exhibit 6 to address such instances.

8 **CONCLUSION**

9 For the foregoing reasons, Plaintiff SIS respectfully requests that the Court grant this
10 motion in limine #5, excluding Intuitive from presenting testimony, documentary evidence,
11 and argument documentary evidence, and argument related to (1) the FDA’s regulatory
12 framework and procedures for clearance of medical devices for commercial marketing, (2)
13 Intuitive’s FDA 510(k) clearance of EndoWrists, (3) the contention that Intuitive’s FDA
14 510(k) clearance of EndoWrists requires adherence to Intuitive use limits; (4) the contention
15 that Intuitive’s FDA 510(k) clearance of EndoWrists is evidence that those use limits ensure
16 or relate to patient safety; and (5) the contention that Intuitive’s FDA 510(k) clearance of
17 EndoWrists is evidence of the actual number of times an EndoWrist can be used from an
18 engineering/failure perspective.

19 Dated: October 28, 2024

McCAULLEY LAW GROUP LLC

By: /s/ Joshua Van Hoven
JOSHUA V. VAN HOVEN

21 E-Mail: josh@mccaulleylawgroup.com
22 3001 Bishop Dr., Suite 300
23 San Ramon, California 94583
Telephone: 925.302.5941

24 RICHARD T. MCCAULLEY (*pro hac vice*)
25 E-Mail: richard@mccaulleylawgroup.com
26 180 N. Wabash Avenue, Suite 601
Chicago, Illinois 60601
Telephone: 312.330.8105

27 *Attorneys for Plaintiff and Counter-Defendant,*
SURGICAL INSTRUMENT SERVICE
28 COMPANY, INC.

CERTIFICATE OF SERVICE

I hereby certify that on October 28, 2024, I caused a copy of the foregoing
PLAINTIFF SIS's MOTION IN LIMINE #5, to be electronically to be served *via*
electronic mail to counsel of record:

Crystal Lohmann Parker

Paul, Weiss, Rifkind, Wharton & Garrison LLP
1285 Avenue of the Americas
New York, NY 10019
212-373-3000
Email: cparker@paulweiss.com

Joshua Hill, Jr.

Paul, Weiss, Rifkind, Wharton & Garrison LLP
535 Mission Street, 24th Floor
San Francisco, CA 94105
(628) 432-5123
Email: jhill@paulweiss.com

Kenneth A. Gallo

Paul, Weiss, Rifkind, Wharton & Garrison LLP
2001 K Street NW
Washington, DC 20006-104 7
202-223-7356
Fax: 202-204-7356
Email: kgallo@paulweiss.com

Paul David Brachman

Paul, Weiss, Rifkind, Wharton & Garrison LLP
2001 K St., NW
Washington, DC 20006
202-223-7440
Email: pbrachman@paulweiss.com

William Michael

Paul, Weiss, Rifkind, Wharton and Garrison LLP
1285 Avenue of the Americas
New York, NY 10019
212-373-3000
Email: WMichael@paulweiss.com

Allen Ruby

Attorney at Law
15559 Union Ave. #138
Los Gatos, CA 95032
408-4 77-9690
Email: allen@allenruby.com

1 **Andrew David Lazerow**
Covington & Burling LLP
2 One CityCenter
850 Tenth Street, NW
3 Washington, DC 20001-4956
202-662-5081
4 Email: alazerow@cov.com

5 **Kathryn Elizabeth Cahoy**
Covington & Burling LLP
6 3000 El Camino Real
5 Palo Alto Square, 10th Floor
7 Palo Alto, CA 94306
650-632-4700
8 Email: kcahoy@cov.com

9 **Sonya Diane Winner**
Covington & Burling LLP
10 Floor 54
415 Mission Street
11 San Francisco, CA 94105-2533
(415) 591-6000
12 Email: swinner@cov.com

13
14 Dated: October 28, 2024

By: /s/ Joshua Van Hoven
JOSHUA V. VAN HOVEN

1 **MCCAULLEY LAW GROUP LLC**
JOSHUA V. VAN HOVEN (CSB No. 262815)
2 E-Mail: josh@mccaulleylawgroup.com
3001 Bishop Dr., Suite 300
3 San Ramon, California 94583
Telephone: 925.302.5941

4 **RICHARD T. MCCAULLEY** (*pro hac vice*)
5 E-Mail: richard@mccaulleylawgroup.com
180 N. Wabash Avenue, Suite 601
6 Chicago, Illinois 60601
Telephone: 312.330.8105

7 *Attorneys for Plaintiff and Counter-Defendant,*
8 **SURGICAL INSTRUMENT SERVICE COMPANY, INC.**

9 **UNITED STATES DISTRICT COURT**
10 **NORTHERN DISTRICT OF CALIFORNIA**

11 **SURGICAL INSTRUMENT SERVICE**
12 **COMPANY, INC.**

13 *Plaintiff/Counter-Defendant,*

14 v.

15 **INTUITIVE SURGICAL, INC.**

16 *Defendant/Counterclaimant.*

CASE NO. 3:21-CV-03496-AMO

Honorable Araceli Martínez-Olguín

**DECLARATION OF JOSHUA VAN
HOVEN IN SUPPORT OF
PLAINTIFF SIS's MOTION IN
LIMINE #5**

1 I, JOSHUA VAN HOVEN, declare as follows:

2 I am an attorney at the law firm of MCCAULLEY LAW GROUP LLC, attorneys for
3 Plaintiff SURGICAL INSTRUMENT SERVICE COMPANY, INC. (“SIS”) in this matter. I
4 have personal knowledge of the matters set forth herein, unless otherwise noted.

- 5 1. Attached as Exhibit 1 is a true and correct copy of a document containing
6 Intuitive’s List of Trial Exhibits, which is dated September 23, 2024, which was
7 provided by Intuitive in this case.
 - 8 2. Attached as Exhibit 2 is a true and correct copy of a document containing
9 Intuitive’s Preliminary Witness List, which is dated October 8, 2024, which was
10 provided by Intuitive in this case.
 - 11 3. Attached as Exhibit 3 is a true and correct copy of a redacted version of the Expert
12 Report of Christy Foreman, MBE, an Intuitive expert in this case, which is dated
13 January 18, 2023 - the portions that are attached hereto were previously filed on
14 the public docket at Dkt. 229-37.
 - 15 4. Attached as Exhibit 4 is a true and correct copy of a redacted version of the Expert
16 Report of Robert D Howe, PhD., an Intuitive expert in this case, which is dated
17 January 18, 2023 - the portions that are attached hereto were previously filed on
18 the public docket at Dkt. 229-29.
 - 19 5. Attached as Exhibit 5 is a true and correct copy of Intuitive’s Draft Proposed Jury
20 Instructions, which is dated September 25, 2024, which was provided by Intuitive
21 in this case.
 - 22 6. Attached as Exhibit 6 is a true and correct copy of SIS’s Proposed
23 Limiting/Cautionary Jury Instructions.
- 24
25
26
27
28

1
2 I declare under the penalty of perjury under the laws of the United States that the
3 foregoing is true and correct.

4 Dated: October 28, 2024

McCAULLEY LAW GROUP LLC
By: /s/ Joshua Van Hoven
JOSHUA V. VAN HOVEN

6 E-Mail: josh@mccaulleylawgroup.com
3001 Bishop Dr., Suite 300
7 San Ramon, California 94583
Telephone: 925.302.5941

8 RICHARD T. MCCAULLEY (*pro hac vice*)
9 E-Mail: richard@mccaulleylawgroup.com
180 N. Wabash Avenue, Suite 601
10 Chicago, Illinois 60601
Telephone: 312.330.8105

11 *Attorneys for Plaintiff and Counter-Defendant,*
12 SURGICAL INSTRUMENT SERVICE
13 COMPANY, INC.

CERTIFICATE OF SERVICE

I hereby certify that on October 28, 2024, I caused a copy of the foregoing

DECLARATION OF JOSHUA VAN HOVEN IN SUPPORT OF PLAINTIFF SIS's

MOTION IN LIMINE #5, to be electronically to be served *via* electronic mail to counsel of record:

Crystal Lohmann Parker

Paul, Weiss, Rifkind, Wharton & Garrison LLP
1285 Avenue of the Americas
New York, NY 10019
212-373-3000
Email: cparker@paulweiss.com

Joshua Hill, Jr.

Paul, Weiss, Rifkind, Wharton & Garrison LLP
535 Mission Street, 24th Floor
San Francisco, CA 94105
(628) 432-5123
Email: jhill@paulweiss.com

Kenneth A. Gallo

Paul, Weiss, Rifkind, Wharton & Garrison LLP
2001 K Street NW
Washington, DC 20006-104 7
202-223-7356
Fax: 202-204-7356
Email: kgallo@paulweiss.com

Paul David Brachman

Paul, Weiss, Rifkind, Wharton & Garrison LLP
2001 K St., NW
Washington, DC 20006
202-223-7440
Email: pbrachman@paulweiss.com

William Michael

Paul, Weiss, Rifkind, Wharton and Garrison LLP
1285 Avenue of the Americas
New York, NY 10019
212-373-3000
Email: WMichael@paulweiss.com

Allen Ruby

Attorney at Law
15559 Union Ave. #138
Los Gatos, CA 95032
408-4 77-9690
Email: allen@allenruby.com

1 **Andrew David Lazerow**
Covington & Burling LLP
2 One CityCenter
850 Tenth Street, NW
3 Washington, DC 20001-4956
202-662-5081
4 Email: alazerow@cov.com

5 **Kathryn Elizabeth Cahoy**
Covington & Burling LLP
6 3000 El Camino Real
5 Palo Alto Square, 10th Floor
7 Palo Alto, CA 94306
650-632-4700
8 Email: kcahoy@cov.com

9 **Sonya Diane Winner**
Covington & Burling LLP
10 Floor 54
415 Mission Street
11 San Francisco, CA 94105-2533
(415) 591-6000
12 Email: swinner@cov.com

13
14 Dated: October 28, 2024

By: /s/ Joshua Van Hoven
JOSHUA V. VAN HOVEN

Exhibit 1

Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc. Civ. No. 21-03496 (AMO) (N.D. Cal.)
 Defendant's List of Trial Exhibits as of September 23, 2024

Defendant's Reservation of Rights: Defendant may introduce some or all of the exhibits on this Exhibit List. Defendant reserves the right to supplement or amend this Exhibit List in light of Plaintiff's objections and Plaintiff's list of exhibits. Defendant specifically reserves the right to supplement or amend this list to incorporate materials identified in Defendant's counter-designations of deposition testimony and completeness objections to Plaintiff's designations and counter-designations of deposition testimony. Defendant also reserves the right to supplement or amend this Exhibit List in light of, among other things, Plaintiff's trial witness list; the Court's pre-trial and trial evidentiary rulings; the arguments and evidence offered by Plaintiff in its case-in-chief; and additional pre-trial discovery in this action, should any be ordered. This Exhibit List does not include all documents that Defendant may use for impeachment, to refresh recollection, or in rebuttal. Defendant reserves the right to offer into evidence summary, demonstrative, blow-up, handout, or composite exhibits. In addition, Defendant reserves the right to introduce any exhibit on Plaintiff's list of exhibits. The inclusion of exhibits on this Exhibit List does not waive any objections available under the Federal Rules of Evidence or otherwise that Defendant may have to the introduction of such exhibit if offered by Plaintiff. Gaps in Defendant's exhibit numbers are the result of Defendant's efforts to match the exhibit number assigned to a document introduced during a deposition.

Def.'s Temporary Exhibit No.	Description	Date	BegBates	EndBates	Objections
DX0012	Franciscan Alliance, Inc. Minutes of The Capital Allocation Committee Meeting.	09/01/2016	FRANCISCAN-00055639	FRANCISCAN-00055648	
DX0030	Email from S. Sosa-Guerrero to J. Szatkiewicz re contract da Vinci, with attachment.	06/09/2017	LARKIN-00025487	LARKIN-00025500	
DX0034	Email chain ending with email from S. Sosa-Guerrero to B. Yuen et al. re Robotic Financial Meeting, with attachment.	11/17/2017	LARKIN-00026343	LARKIN-00026346	
DX0054	Email chain ending with email from J. Wagner to J. Landers et al. re Xi Robot.	08/23/2019	VMC-00014375	VMC-00014380	
DX0056	Email chain ending with email from J. Wagner to M. Burke re any updates on the robot?, with attachments.	08/23/2018	VMC-00015993	VMC-00016060	
DX0095	Email from P. Garcia to J. Gonzalez re Meeting with Dr. Estape.	04/03/2019	LARKIN-00013651	LARKIN-00013651	
DX0106	Email chain ending with email from J. Wagner to L. Dillingham re Xi quote request for Valley Medical Center, with attachments.	04/06/2018	VMC-00021270	VMC-00021281	

Compilation of Intuitive Form 10-K Filings			
Def.'s Temporary Exhibit No.	Description	Date	Objections
DX1765.01	Intuitive Surgical Form 10-K - FY 2000	3/30/2001	
DX1765.02	Intuitive Surgical Form 10-K - FY 2001	3/30/2002	
DX1765.03	Intuitive Surgical Form 10-K - FY 2002	2/28/2003	
DX1765.04	Intuitive Surgical Form 10-K - FY 2003	2/29/2004	
DX1765.05	Intuitive Surgical Form 10-K - FY 2004	2/28/2005	
DX1765.06	Intuitive Surgical Form 10-K - FY 2005	2/28/2006	
DX1765.07	Intuitive Surgical Form 10-K - FY 2006	1/31/2007	
DX1765.08	Intuitive Surgical Form 10-K - FY 2007	1/31/2008	
DX1765.09	Intuitive Surgical Form 10-K - FY 2008	1/31/2009	
DX1765.10	Intuitive Surgical Form 10-K - FY 2009	1/21/2010	
DX1765.11	Intuitive Surgical Form 10-K - FY 2010	1/20/2011	
DX1765.12	Intuitive Surgical Form 10-K - FY 2011	1/20/2012	
DX1765.13	Intuitive Surgical Form 10-K - FY 2012	1/18/2012	
DX1765.14	Intuitive Surgical Form 10-K - FY 2013	1/17/2014	
DX1765.15	Intuitive Surgical Form 10-K - FY 2014	1/16/2015	
DX1765.16	Intuitive Surgical Form 10-K - FY 2015	1/19/2016	
DX1765.17	Intuitive Surgical Form 10-K - FY 2016	2/3/2017	
DX1765.18	Intuitive Surgical Form 10-K - FY 2017	1/19/2018	
DX1765.19	Intuitive Surgical Form 10-K - FY 2018	1/18/2019	
DX1765.20	Intuitive Surgical Form 10-K - FY 2019	1/17/2020	
DX1765.21	Intuitive Surgical Form 10-K - FY 2020	1/15/2021	
DX1765.22	Intuitive Surgical Form 10-K - FY 2021	1/26/2022	
DX1765.23	Intuitive Surgical Form 10-K - FY 2022	2/7/2023	

	A	B	C	D	E	F
1	Compilation of Early Intuitive Customer Contracts.					
2	Def.'s Temporary Exhibit No.	Description	Date	Beg Bates	End Bates	Objections
3	DX1766.01	Sales Agreement between Intuitive Surgical, Inc. and The Ohio State University	07/01/1999	Intuitive-01529190	Intuitive-01529218	
4	DX1766.02	Sales Agreement with Amendment 1, Pitt County Memorial Hospital	10/20/1999	Intuitive-01291299	Intuitive-01291327	
5	DX1766.03	Sales and Service Agreement No 18 between Intuitive Surgical and Providence Health System	02/10/2000	Intuitive-01281282	Intuitive-01281308	
6	DX1766.04	Sales and Service Agreement between Intuitive Surgical and San	05/04/2000	Intuitive-01524785	Intuitive-01524812	
7	DX1766.05	Sales and Service Agreement between Intuitive Surgical, Inc. and	05/11/2000	Intuitive-02016009	Intuitive-02016035	
8	DX1766.06	Sales and Service Agreement between Intuitive Surgical and The Johns Hopkins Hospital	07/31/2000	Intuitive-01524624	Intuitive-01524655	
9	DX1766.07	Sales and Service Agreement between Intuitive Surgical and the Board of Trustees of the University of Illinois	08/29/2000	Intuitive-01524477	Intuitive-01524506	
10	DX1766.08	Sales and Service Agreement between Intuitive Surgical, Inc. and The University of Texas Medical Branch at Galveston	08/31/2000	Intuitive-02016152	Intuitive-02016181	
11	DX1766.09	Sales and Service Agreement between Intuitive Surgical and Ohio State University	10/20/2000	Intuitive-01524683	Intuitive-01524732	
12	DX1766.10	Sales and Service Agreement between Intuitive Surgical and Hackensack University Medical Center	10/30/2000	Intuitive-01524570	Intuitive-01524595	
13	DX1766.11	Sales and Service Agreement between Intuitive Surgical and Maimonides Medical Center	11/29/2000	Intuitive-01525071	Intuitive-01525120	
14	DX1766.12	Sales and Service Agreement between Intuitive Surgical and Valley Hospital	12/01/2000	Intuitive-01282449	Intuitive-01282476	
15	DX1766.13	Sales and Service Agreement between Intuitive Surgical, Inc. and Tenet HealthSystem Hospitals d.b.a. USC University Hospital	02/12/2001	Intuitive-02016098	Intuitive-02016121	
16	DX1766.14	Sales and Service Agreement between Intuitive Surgical, Inc. and The Board of Trustees of the University of Alabama, on behalf of its operating unit, University of Alabama Hospital	03/15/2001	Intuitive-01611639	Intuitive-01611664	
17	DX1766.15	Sales and Service Agreement between Intuitive Surgical, Inc. and The University of Michigan Medical Center	05/18/2001	Intuitive-02016068	Intuitive-02016089	
18	DX1766.16	Sales and Service Agreement between Intuitive Surgical, Inc. and USC University Hospital, Inc. d.b.a. USC University Hospital	08/14/2001	Intuitive-02005508	Intuitive-02005527	
19	DX1766.17	Sales and Service Agreement between Intuitive Surgical and St. Luke's Medical Center	08/21/2001	Intuitive-01525269	Intuitive-01525299	
20	DX1766.18	Sales and Service Agreement between Intuitive Surgical, Inc. and Saint Agnes Medical Center	08/21/2001	Intuitive-01612217	Intuitive-01612234	
21	DX1766.19	Sales and Service Agreement between Intuitive Surgical and St. Luke's Episcopal Hospital	08/29/2001	Intuitive-01525233	Intuitive-01525248	
22	DX1766.20	Sales and Service Agreement between Intuitive Surgical, Inc. and Virginia Mason Medical Center	08/30/2001	Intuitive-01291228	Intuitive-01291245	
23	DX1766.21	Sales and Service Agreement between Intuitive Surgical and Creighton Saint Joseph Regional Healthcare System	09/07/2001	Intuitive-01524978	Intuitive-01524993	
24	DX1766.22	Sales and Service Agreement between Intuitive Surgical, Inc. and Shawnee Mission Medical Center	09/18/2001	Intuitive-02015965	Intuitive-02015980	
25	DX1766.23	Sales and Service Agreement between Intuitive Surgical and New York Presbyterian Hospital	09/25/2001	Intuitive-01525160	Intuitive-01525186	
26	DX1766.24	Sales and Service Agreement between Intuitive Surgical and Walter Reed Army Hospital	09/30/2001	Intuitive-01525390	Intuitive-01525410	
27	DX1766.25	Amendment Number 1 to the Distribution Agreement Between Intuitive Surgical, Inc. and AB Medica S.R.L.	10/09/2001	Intuitive-01530721	Intuitive-01530723	
28	DX1766.26	Amendment Number 1 to the Service Support Agreement between Intuitive Surgical, Inc. and AB Medica S.R.L.	10/09/2001	Intuitive-01532513	Intuitive-01532514	
29	DX1766.27	Sales and Service Agreement between Intuitive Surgical, Inc. and Scottsdale Healthcare Shea Administration	11/16/2001	Intuitive-01622889	Intuitive-01622905	
30	DX1766.28	Master Purchase and Master Service Agreement between Intuitive Surgical and St. Luke's Hospital	11/19/2001	Intuitive-01299770	Intuitive-01299788	
31	DX1766.29	Sales and Service Agreement between Intuitive Surgical and Saint Alphonsus Regional Medical Center	12/06/2001	Intuitive-01525214	Intuitive-01525232	
32	DX1766.30	Sales and Service Agreement No 128-2000 between Intuitive Surgical and Inova Fairfax Hospital	12/21/2001	Intuitive-01278261	Intuitive-01278290	
33	DX1766.31	Sales and Service Agreement between Intuitive Surgical and Fresno Community Hospital	12/28/2001	Intuitive-01525017	Intuitive-01525033	
34	DX1766.32	Sales and Service Agreement between Intuitive Surgical and The Mount Sinai Hospital	01/17/2002	Intuitive-01525965	Intuitive-01525982	
35	DX1766.33	Sales and Service Agreement between Intuitive Surgical and Children's Hospital	01/23/2002	Intuitive-01525525	Intuitive-01525541	
36	DX1766.34	Ethicon Endo-Surgery, Inc Use Agreement between Intuitive Surgical, Inc. and Ethicon Endo-Surgery, Inc.	01/25/2002	Intuitive-02021458	Intuitive-02021465	

	A	B	C	D	E	F
37	DX1766.35	Assignment and Assumption Agreement between Self Regional Healthcare, North Carolina Baptist Hospital, and Intuitive Surgical, Inc.	01/25/2002	Intuitive-02022733	Intuitive-02022750	
38	DX1766.36	Sales and Service Agreement between Intuitive Surgical and University of California at San Francisco	02/08/2002	Intuitive-01525988	Intuitive-01526004	
39	DX1766.37	Sales and Service Agreement between Intuitive Surgical, Inc. and Baptist Health Systems of South Florida	02/12/2002	Intuitive-01611396	Intuitive-01611413	
40	DX1766.38	Sales and Service Agreement between Intuitive Surgical and Park Place Medical Center	02/20/2002	Intuitive-01285756	Intuitive-01285773	
41	DX1766.39	Sales and Service Agreement between Intuitive Surgical and Catholic Medical Center	02/20/2002	Intuitive-01525452	Intuitive-01525466	
42	DX1766.40	Sales and Service Agreement between Intuitive Surgical and The Mayo Clinic	03/08/2002	Intuitive-01525629	Intuitive-01525653	
43	DX1766.41	Sales and Service Agreement between Intuitive Surgical and University of California Irvine Medical Center	03/13/2002	Intuitive-01526045	Intuitive-01526062	
44	DX1766.42	Sales and Service Agreement between Intuitive Surgical and Central Iowa Hospital Corporation	03/25/2002	Intuitive-01525509	Intuitive-01525524	
45	DX1766.43	Sales and Service Agreement between Intuitive Surgical and St. Joseph's Hospital	03/25/2002	Intuitive-01525893	Intuitive-01525907	
46	DX1766.44	Sales and Service Agreement between Intuitive Surgical and New York University Medical Center	04/05/2002	Intuitive-01525734	Intuitive-01525749	
47	DX1766.45	Sales and Service Agreement between Intuitive Surgical and Alliance Hospital of Odessa Texas	05/19/2002	Intuitive-01525434	Intuitive-01525451	
48	DX1766.46	Sales and Service Agreement between Intuitive Surgical and Memorial Hermann Hospital	05/20/2002	Intuitive-01525675	Intuitive-01525693	
49	DX1766.47	Loan Agreement between Intuitive Surgical, Inc. and University of California at San Francisco	06/05/2002	Intuitive-02005250	Intuitive-02005253	
50	DX1766.48	Sales and Service Agreement between Intuitive Surgical and University of Iowa Hospital and Clinics	06/20/2002	Intuitive-01526028	Intuitive-01526044	
51	DX1766.49	Sales and Service Agreement between Intuitive Surgical, Inc. and Trustees of the University of Pennsylvania	06/21/2002	Intuitive-01530011	Intuitive-01530030	
52	DX1766.50	Sales and Service Agreement between Intuitive Surgical and Peoria Surgical Group	06/24/2002	Intuitive-01525774	Intuitive-01525789	
53	DX1766.51	Sales and Service Agreement between Intuitive Surgical and John Muir/Mt. Diablo Health System	06/27/2002	Intuitive-01525717	Intuitive-01525733	
54	DX1766.52	Sales and Service Agreement between Intuitive Surgical and St. Joseph's Hospital of Atlanta	07/18/2002	Intuitive-01525834	Intuitive-01525852	
55	DX1766.53	Sales and Service Agreement between Intuitive Surgical, Inc. and Hamot Health Foundation	07/30/2002	Intuitive-01611414	Intuitive-01611429	
56	DX1766.54	Sales and Service Agreement between Intuitive Surgical and Memorial Hermann Hospital	08/30/2002	Intuitive-01525654	Intuitive-01525674	
57	DX1766.55	Sales and Service Agreement between Intuitive Surgical, Inc. and Queen of the Valley Hospital	09/04/2002	Intuitive-02015843	Intuitive-02015858	
58	DX1766.56	Master Agreement between Intuitive Surgical, Inc. and HCA Management Services LP	09/18/2002	Intuitive-02021376	Intuitive-02021406	
59	DX1766.57	Amendment Number 1 To The Sales and Service Agreement between Intuitive Surgical, Inc. and CHCA Woman's Hospital, L.P. / dba Woman's Hospital of Texas	09/25/2002	Intuitive-01611248	Intuitive-01611249	
60	DX1766.58	Sales and Service Agreement between Intuitive Surgical, Inc. and Marion Community Hospital, Incorporated, a Florida Corporation, /dba Ocala Regional Medical Center	09/25/2002	Intuitive-01622658	Intuitive-01622679	
61	DX1766.59	Amendment Number 1 To The Sales and Service Agreement between Intuitive Surgical, Inc. and CHCA Woman's Hospital, L.P. / dba Woman's Hospital of Texas	09/25/2002	Intuitive-02005356	Intuitive-02005357	
62	DX1766.60	Sales and Service Agreement between Intuitive Surgical and Cedars Healthcare Group	09/26/2002	Intuitive-01525467	Intuitive-01525486	
63	DX1766.61	Sales and Service Agreement between Intuitive Surgical, Inc. and Sunrise Hospital and Medical Center, LLC /dba Sunrise Hospital and Medical Center	09/26/2002	Intuitive-01622700	Intuitive-01622719	
64	DX1766.62	Sales and Service Agreement between Intuitive Surgical and Medical College of Pennsylvania Hospital	09/27/2002	Intuitive-01525875	Intuitive-01525891	
65	DX1766.63	Sales and Service Agreement between Intuitive Surgical, Inc. and CHCA Woman's Hospital, L.P. /dba Woman's Hospital of Texas	09/30/2002	Intuitive-01611226	Intuitive-01611245	
66	DX1766.64	Sales and Service Agreement between Intuitive Surgical and HCA Health Services of Florida	10/17/2002	Intuitive-01285445	Intuitive-01285464	
67	DX1766.65	Sales and Service Agreement between Intuitive Surgical, Inc. and University Healthcare System, LC, d/d/a Tulane University Hospital and Clinic	10/22/2002	Intuitive-02005375	Intuitive-02005394	
68	DX1766.66	Sales and Service Agreement between Intuitive Surgical, Inc. and Largo Medical Center, Inc., /dba Largo Medical Center	10/23/2002	Intuitive-01611448	Intuitive-01611468	
69	DX1766.67	Sales and Service Agreement between Intuitive Surgical, Inc. and HCA-HealthONE LLC /dba Presbyterian/St. Luke's Medical Center	10/31/2002	Intuitive-01622680	Intuitive-01622699	

	A	B	C	D	E	F
70	DX1766.68	Amendment Number 1 To The Sales and Service Agreement Number 091801-SMMM between Intuitive Surgical, Inc. and Shawnee Mission Medical Center	11/08/2002	Intuitive-02015981	Intuitive-02015981	
71	DX1766.69	Sales and Service Agreement between Intuitive Surgical and Columbia Hospital at Medical City Dallas	12/03/2002	Intuitive-01525581	Intuitive-01525600	
72	DX1766.70	Sales and Service Agreement between Intuitive Surgical, Inc. and New York City Health and Hospitals	12/19/2002	Intuitive-01612542	Intuitive-01612572	
73	DX1766.71	Sales and Service Agreement No 121902 between Intuitive Surgical and Salt Lake Regional Medical Center	12/20/2002	Intuitive-01280979	Intuitive-01280994	
74	DX1766.72	Sales and Service Agreement between Intuitive Surgical and Newark Beth Israel Medical Center	12/20/2002	Intuitive-01525750	Intuitive-01525766	
75	DX1766.73	Sales and Service Agreement between Intuitive Surgical and Children's Hospital	12/23/2002	Intuitive-01525542	Intuitive-01525561	
76	DX1766.74	Sales and Service Agreement between Intuitive Surgical, Inc. and HCA Health Services of Virginia, Inc. D/b/a Henrico Doctors' Hospital	12/23/2002	Intuitive-02015755	Intuitive-02015772	
77	DX1766.75	Sales and Service Agreement between Intuitive Surgical, Inc. and Coliseum Medical Center, LLC /dba Coliseum Medical Centers	01/24/2003	Intuitive-01613087	Intuitive-01613105	
78	DX1766.76	Sales and Service Agreement between Intuitive Surgical, Inc. and BryanLGH Medical Center	03/07/2003	Intuitive-01622848	Intuitive-01622864	
79	DX1766.77	Sales and Service Agreement between Intuitive Surgical and The Children's Hospital Association	03/24/2003	Intuitive-01526633	Intuitive-01526646	
80	DX1766.78	Sales and Service Agreement between Intuitive Surgical and South Broward Hospital District D/B/A Memorial Regional Hospital	03/27/2003	Intuitive-01526437	Intuitive-01526454	
81	DX1766.79	Sales and Service Agreement between Intuitive Surgical and Arkansas Children's Hospital	03/31/2003	Intuitive-01526122	Intuitive-01526136	
82	DX1766.80	Sales and Service Agreement between Intuitive Surgical and Vanderbilt University Medical Center	03/31/2003	Intuitive-01526872	Intuitive-01526888	
83	DX1766.81	Master Group Purchasing Agreement between HealthTrust Purchasing Group and Intuitive Surgical, Inc.	05/01/2003	Intuitive-02021318	Intuitive-02021363	
84	DX1766.82	Rental Agreement between Intuitive Surgical, Inc. and Brigham and Women's Hospital	05/28/2003	Intuitive-02016198	Intuitive-02016199	
85	DX1766.83	Sales and Service Agreement between Intuitive Surgical All Children's Hospital	06/05/2003	Intuitive-01526101	Intuitive-01526119	
86	DX1766.84	Sales and Service Agreement between Intuitive Surgical and University of Virginia	06/05/2003	Intuitive-01526811	Intuitive-01526836	
87	DX1766.85	Business Associate Addendum between Intuitive Surgical, Inc. and The Rector and Visitors of the University of Virginia	06/05/2003	Intuitive-02015652	Intuitive-02015658	
88	DX1766.86	Sales and Service Agreement between Intuitive Surgical and City of Hope National Medical Center	06/10/2003	Intuitive-01526216	Intuitive-01526233	
89	DX1766.87	Loaner Agreement between Intuitive Surgical, Inc. and Ohio State University	06/10/2003	Intuitive-02005654	Intuitive-02005655	
90	DX1766.88	Amendment Number 1 to the Intuitive Surgical Inc. Sales and Service Agreement between Intuitive Surgical and Clarian Health Partners	06/19/2003	Intuitive-01285439	Intuitive-01285439	
91	DX1766.89	Sales and Service Agreement between Intuitive Surgical and Baptist Memorial Hospital	06/20/2003	Intuitive-01526142	Intuitive-01526166	
92	DX1766.90	Sales and Service Agreement between Intuitive Surgical and Saint Thomas Health Services	06/25/2003	Intuitive-01284965	Intuitive-01284982	
93	DX1766.91	Addendum to Sales and Service Agreement between Intuitive Surgical and the Good Samaritan Hospital	06/25/2003	Intuitive-01526321	Intuitive-01526328	
94	DX1766.92	Sales and Service Agreement between Intuitive Surgical and The Good Samaritan Hospital	06/25/2003	Intuitive-01526647	Intuitive-01526671	
95	DX1766.93	Sales and Service Agreement between Intuitive Surgical and Urology Associates of North Texas	06/26/2003	Intuitive-01526857	Intuitive-01526871	
96	DX1766.94	Sales and Service Agreement between Intuitive Surgical and Fairview Health Services	06/27/2003	Intuitive-01526286	Intuitive-01526304	
97	DX1766.95	Fax message from Gulf Medical Co to Intuitive Surgical re: Transaction Agreement	06/27/2003	Intuitive-01526335	Intuitive-01526337	
98	DX1766.96	Sales and Service Agreement between Intuitive Surgical and Saint Joseph's Health System	06/27/2003	Intuitive-01526581	Intuitive-01526599	
99	DX1766.97	Sales and Service Agreement between Intuitive Surgical and Lucile Packard Children's Hospital	09/09/2003	Intuitive-01526405	Intuitive-01526420	
100	DX1766.98	Sales and Service Agreement between Intuitive Surgical and St. John's Mercy Health System	09/15/2003	Intuitive-01526600	Intuitive-01526615	
101	DX1766.99	Sales and Service Agreement between Intuitive Surgical, Inc. and University Hospital, Inc.	09/21/2003	Intuitive-02005462	Intuitive-02005477	
102	DX1766.100	Sales and Service Agreement between Intuitive Surgical and St. Joseph Mercy of Macomb and Trinity Health System	09/22/2003	Intuitive-01526616	Intuitive-01526632	
103	DX1766.101	Sales and Service Agreement between Intuitive Surgical and University of Cincinnati	09/24/2003	Intuitive-01526744	Intuitive-01526759	

	A	B	C	D	E	F
104	DX1766.102	Sales and Service Agreement between Intuitive Surgical and Central DuPage Health	09/25/2003	Intuitive-01526183	Intuitive-01526199	
105	DX1766.103	Sales and Service Agreement between Intuitive Surgical, Inc. and Alta Bates Summit Medical Center	09/25/2003	Intuitive-01611207	Intuitive-01611225	
106	DX1766.104	Sales and Service Agreement between Intuitive Surgical and Maine Medical Center	09/26/2003	Intuitive-01468748	Intuitive-01468763	
107	DX1766.105	Sales and Service Agreement between Intuitive Surgical and Regents of the University of California UC Davis Health System	09/29/2003	Intuitive-01526527	Intuitive-01526545	
108	DX1766.106	Sales and Service Agreement between Intuitive Surgical and George Washington University Hospital	09/30/2003	Intuitive-01526305	Intuitive-01526320	
109	DX1766.107	Sales and Service Agreement between Intuitive Surgical, Inc. and TCC Partners d/b/a/ The Cleveland Clinic Hospital	09/30/2003	Intuitive-01622814	Intuitive-01622829	
110	DX1766.108	Sales and Service Agreement between Intuitive Surgical and University of Washington Medical Center	10/13/2003	Intuitive-01526837	Intuitive-01526856	
111	DX1766.109	Sales and Service Agreement between Intuitive Surgical and North Shore University Hospital	10/14/2003	Intuitive-01526507	Intuitive-01526522	
112	DX1766.110	Sales and Service Agreement between Intuitive Surgical and Christus Schumpert Health System	11/21/2003	Intuitive-01526200	Intuitive-01526215	
113	DX1766.111	Amendment No. 1 to the Distribution Agreement between Intuitive Surgical, Inc. and Transmedic Pte, Ltd.	12/05/2003	Intuitive-01533794	Intuitive-01533794	
114	DX1766.112	Intuitive Surgical Training Center Agreement between Intuitive Surgical, Inc. and The Regents of the University of Minnesota	12/12/2003	Intuitive-02020198	Intuitive-02020202	
115	DX1766.113	Sales and Service Agreement between Intuitive Surgical and the Regents of the University of Minnesota	12/15/2003	Intuitive-01526672	Intuitive-01526691	
116	DX1766.114	Sales and Service Agreement between Intuitive Surgical and University of Kentucky	12/16/2003	Intuitive-01526776	Intuitive-01526790	
117	DX1766.115	Transaction Agreement Between Transmedic Pte, Ltd. And Intuitive Surgical, Inc.	12/17/2003	Intuitive-01616253	Intuitive-01616254	
118	DX1766.116	Sales and Service Agreement between Intuitive Surgical and Cedars-Sinai Medical Center	12/19/2003	Intuitive-01526167	Intuitive-01526182	
119	DX1766.117	Sales and Service Agreement between Intuitive Surgical and Rochester General Hospital	12/19/2003	Intuitive-01526565	Intuitive-01526580	
120	DX1766.118	Sales and Service Agreement between Intuitive Surgical and Washington Township Health Care District	12/19/2003	Intuitive-01526891	Intuitive-01526911	
121	DX1766.119	Zeus Technology Agreement between Intuitive Surgical, Inc. and University of Washington	12/23/2003	Intuitive-02015558	Intuitive-02015567	
122	DX1766.120	Sales and Service Agreement between Intuitive Surgical and Mother Frances Hospital Regional Health Care Center	12/24/2003	Intuitive-01526473	Intuitive-01526488	
123	DX1766.121	Amendment Number 1 to the Sales and Service Agreement Between Saint Joseph's Hospital of Atlanta and Intuitive Surgical	01/16/2004	Intuitive-01525892	Intuitive-01525892	
124	DX1766.122	Sales and Service Agreement between Intuitive Surgical, Inc. and St. Peter's Hospital of the city of Albany	02/13/2004	Intuitive-01527808	Intuitive-01527824	
125	DX1766.123	Sales and Service Agreement between Intuitive Surgical and The Mayo Clinic	2/26/2004	Intuitive-01527876	Intuitive-01527891	
126	DX1766.124	Amendment No. 2 to the Distribution Agreement between Intuitive Surgical, Inc. and Transmedic Pte, Ltd.	03/11/2004	Intuitive-01533797	Intuitive-01533800	
127	DX1766.125	Sales and Service Agreement between Intuitive Surgical and St. Mary's/Duluth Clinic Health System	03/24/2004	Intuitive-01365260	Intuitive-01365276	
128	DX1766.126	Sales and Service Agreement between Intuitive Surgical, Inc. and Adventist Health System/Sunbelt, Inc., /dba Florida Hospital	03/29/2004	Intuitive-01526932	Intuitive-01526947	
129	DX1766.127	Terms and Conditions between Intuitive Surgical, Inc. and Riverside Medical Center	03/29/2004	Intuitive-02015413	Intuitive-02015418	
130	DX1766.128	Sales and Service Agreement between Intuitive Surgical, Inc. and Lakeland Regional Medical Center, Inc.	03/30/2004	Intuitive-01527329	Intuitive-01527352	
131	DX1766.129	Sales and Service Agreement between Intuitive Surgical, Inc. and Saint Joseph's Health System	03/30/2004	Intuitive-01527599	Intuitive-01527613	
132	DX1766.130	Sales and Service Agreement between Intuitive Surgical, Inc. and Summa Health System Hospitals	03/30/2004	Intuitive-01527825	Intuitive-01527840	
133	DX1766.131	Sales and Service Agreement between Intuitive Surgical, Inc. and HealthEast St. John's Hospital	04/22/2004	Intuitive-01527284	Intuitive-01527300	
134	DX1766.132	Sales and Service Agreement between Intuitive Surgical and Henrico Doctors' Hospital	04/28/2004	Intuitive-01524596	Intuitive-01524623	
135	DX1766.133	Amendment Number 1 to the Sales and Services Agreement between Intuitive Surgical and Clarian Health Partners Inc - Indiana University Hospital	4/29/2004	Intuitive-01285917	Intuitive-01285917	
136	DX1766.134	Amendment Number 2 to the Sales and Services Agreement between Intuitive Surgical and the Methodist University Hospital	05/07/2004	Intuitive-01285444	Intuitive-01285444	
137	DX1766.135	Sales and Service Agreement between Intuitive Surgical and Clarian Health Partners	05/12/2004	Intuitive-01525562	Intuitive-01525580	
138	DX1766.136	Sales and Service Agreement between Intuitive Surgical, Inc. and David Geffen School of Medicine at UCLA	05/12/2004	Intuitive-01527103	Intuitive-01527119	

	A	B	C	D	E	F
139	DX1766.137	Amendment Number 1 to the Sales and Service Agreement between Intuitive Surgical and U of Medicine and Dentistry of New Jersey	05/19/2004	Intuitive-01284959	Intuitive-01284960	
140	DX1766.138	Amendment Number 1 to the Sales and Service Agreement	05/19/2004	Intuitive-01526120	Intuitive-01526121	
141	DX1766.139	Sales and Service Agreement between Intuitive Surgical and University of Medicine and Dentistry of New Jersey	05/19/2004	Intuitive-01526711	Intuitive-01526728	
142	DX1766.140	Sales and Service Agreement between Intuitive Surgical and Centennial Medical Center	05/21/2004	Intuitive-01525489	Intuitive-01525508	
143	DX1766.141	Sales and Service Agreement between Intuitive Surgical and HCA Health Services	05/21/2004	Intuitive-01525606	Intuitive-01525625	
144	DX1766.142	Amendment to the Distribution Agreement Between Intuitive Surgical, Inc. and AB Medica S.p.A.	05/25/2004	Intuitive-01530715	Intuitive-01530720	
145	DX1766.143	Sales and Service Agreement for HPG Participants between Intuitive Surgical, Inc. and VHS San Antonio Partners, L.P. d.b.a. St. Luke's Baptist Health Systems, Baptist Medical Center Campus	06/17/2004	Intuitive-01526948	Intuitive-01526965	
146	DX1766.144	Sales and Service Agreement between Intuitive Surgical, Inc. and City of Hope National Medical Center	06/17/2004	Intuitive-01527035	Intuitive-01527050	
147	DX1766.145	Sales and Service Agreement between Intuitive Surgical, Inc. and Roswell Park Cancer Institute	06/17/2004	Intuitive-01527563	Intuitive-01527577	
148	DX1766.146	Sales and Service Agreement between Intuitive Surgical, Inc. and Poudre Valley Hospital	06/19/2004	Intuitive-02015346	Intuitive-02015363	
149	DX1766.147	Sales and Service Agreement between Intuitive Surgical, Inc. and Hoag Memorial Hospital Presbyterian	06/22/2004	Intuitive-01527301	Intuitive-01527316	
150	DX1766.148	Sales and Service Agreement between Intuitive Surgical, Inc. and Sentara Norfolk General	06/22/2004	Intuitive-01527631	Intuitive-01527648	
151	DX1766.149	Sales and Service Agreement between Intuitive Surgical, Inc. and Fremont Area Medical Center	06/25/2004	Intuitive-01527215	Intuitive-01527232	
152	DX1766.150	Sales and Service Agreement between Intuitive Surgical, Inc. and AHS Hospital Corporation/Morristown Memorial Hospital Campus	06/25/2004	Intuitive-01527421	Intuitive-01527436	
153	DX1766.151	Sales and Service Agreement between Intuitive Surgical, Inc. and Sioux Valley Hospital	06/29/2004	Intuitive-01527665	Intuitive-01527680	
154	DX1766.152	Amendment Number 1 To The Master Agreement between Intuitive Surgical, Inc. and HCA Management Services LP	07/12/2004	Intuitive-02021407	Intuitive-02021410	
155	DX1766.153	Amendment No. 3 to the Distribution Agreement between Intuitive Surgical, Inc. and Transmedic Pte, Ltd.	07/26/2004	Intuitive-01533801	Intuitive-01533801	
156	DX1766.154	Sales and Service Agreement between Intuitive Surgical, Inc. and Sun Health Corporation, for its subsidiary W.O. Boswell Hospital	07/26/2004	Intuitive-02015315	Intuitive-02015330	
157	DX1766.155	Sales Agreement between Intuitive Surgical, Inc. and WakeMed	08/16/2004	Intuitive-01527951	Intuitive-01527971	
158	DX1766.156	Assignment and Assumption Agreement between Tenet Health System and Intuitive Surgical, Inc.	08/17/2004	Intuitive-02022818	Intuitive-02022819	
159	DX1766.157	Amendment Number 1 to the Sales and Service Agreement between Intuitive Surgical and U of Texas Medical Branch at Galveston	08/18/2004	Intuitive-01283057	Intuitive-01283057	
160	DX1766.158	Sales and Service Agreement between Intuitive Surgical and Peoria Surgical Group	08/25/2004	Intuitive-01525767	Intuitive-01525769	
161	DX1766.159	Amendment Number 1 to the Sales and Service Agreement between Intuitive Surgical and Hartford Hospital	08/26/2004	Intuitive-01285350	Intuitive-01285353	
162	DX1766.160	Addendum to the Sales and Services Agreement between Intuitive Surgical, Inc. and Columbia/St. David's Healthcare System	08/30/2004	Intuitive-01527681	Intuitive-01527681	
163	DX1766.161	Sales and Service Agreement Between Intuitive Surgical, Inc. and St. David's Medical Center	08/30/2004	Intuitive-01527682	Intuitive-01527701	
164	DX1766.162	Sales and Service Agreement between Intuitive Surgical, Inc. and Eastern Maine Medical Center	09/03/2004	Intuitive-01527184	Intuitive-01527199	
165	DX1766.163	Sales and Service Agreement for HPG Participants between Intuitive Surgical, Inc. and VHS San Antonio Partners, L.P. d.b.a. St. Luke's Baptist Health Systems	09/03/2004	Intuitive-01527755	Intuitive-01527772	
166	DX1766.164	Sales Agreement between Intuitive Surgical, Inc. and Geisinger Medical Center	09/13/2004	Intuitive-01527233	Intuitive-01527260	
167	DX1766.165	Amendment Number 1 To The Sales and Service Agreement between Intuitive Surgical, Inc. and The Ohio State University on behalf of its University Hospitals	09/14/2004	Intuitive-02005347	Intuitive-02005349	
168	DX1766.166	Sales and Service Agreement between Intuitive Surgical and Hartford Hospital	09/20/2004	Intuitive-01526340	Intuitive-01526360	
169	DX1766.167	Service Amendment to the Service Support Agreement between Intuitive Surgical, Inc. and Transmedic Pte, Ltd.	09/20/2004	Intuitive-01532924	Intuitive-01532924	
170	DX1766.168	Amendment No. 4 to the Distribution Agreement between Intuitive Surgical, Inc. and Transmedic Pte, Ltd.	09/20/2004	Intuitive-01533802	Intuitive-01533804	
171	DX1766.169	Business Associate Agreement between The Presbyterian Hospital and Intuitive Surgical, Inc.	09/28/2004	Intuitive-02005329	Intuitive-02005334	
172	DX1766.170	Sales and Service Agreement between Intuitive Surgical, Inc. and University of Pittsburgh Medical Center	09/29/2004	Intuitive-01527930	Intuitive-01527945	

	A	B	C	D	E	F
173	DX1766.171	Amendment Number 1 To The Sales and Service Agreement between Intuitive Surgical, Inc. and The Johns Hopkins Hospital	10/05/2004	Intuitive-02015942	Intuitive-02015942	
174	DX1766.172	Amendment Number 1 To The Sales and Service Agreement between Intuitive Surgical, Inc. and Pitt County Memorial Hospital	10/12/2004	Intuitive-02022858	Intuitive-02022858	
175	DX1766.173	Sales and Service Agreement between Intuitive Surgical, Inc. and Covenant Health System	10/20/2004	Intuitive-01527083	Intuitive-01527099	
176	DX1766.174	Sales and Service Agreement between Intuitive Surgical, Inc. and Fort Sanders Regional Medical Center	10/21/2004	Intuitive-01527200	Intuitive-01527214	
177	DX1766.175	Distribution Agreement Between Intuitive Surgical, Inc. And Palex Medical SA	10/26/2004	Intuitive-01535611	Intuitive-01535635	
178	DX1766.176	Sales and Service Agreement between Intuitive Surgical, Inc. and Community Memorial Hospital	10/28/2004	Intuitive-01527067	Intuitive-01527082	
179	DX1766.177	Between Fort Sanders Regional Medical Center and Intuitive Surgical, Inc.	11/09/2004	Intuitive-02015190	Intuitive-02015190	
180	DX1766.178	Sales and Service Agreement between Intuitive Surgical, Inc. and Sharp Memorial Hospital	12/02/2004	Intuitive-01527649	Intuitive-01527664	
181	DX1766.179	Sales and Service Agreement between Intuitive Surgical, Inc. and Boston Medical Center	12/08/2004	Intuitive-01526983	Intuitive-01526998	
182	DX1766.180	Sales and Service Agreement between Intuitive Surgical, Inc. and Norton Hospitals, Inc.	12/09/2004	Intuitive-01527472	Intuitive-01527488	
183	DX1766.181	Sales and Service Agreement between Intuitive Surgical, Inc. and Sutter Health Sacramento Sierra Region	12/09/2004	Intuitive-01527858	Intuitive-01527875	
184	DX1766.182	Sales and Service Agreement between Intuitive Surgical, Inc. and Porter Adventist Hospital	12/09/2004	Intuitive-01623877	Intuitive-01623893	
185	DX1766.183	Sales and Service Agreement between Intuitive Surgical, Inc. and Oaklawn Hospital	12/13/2004	Intuitive-01527489	Intuitive-01527504	
186	DX1766.184	Sales and Service Agreement between Intuitive Surgical, Inc. and Mississippi Baptist Medical Center	12/21/2004	Intuitive-01527405	Intuitive-01527420	
187	DX1766.185	Sales and Service Agreement between Intuitive Surgical, Inc. and Mother Frances Hospital Regional Health Care Center	12/21/2004	Intuitive-01527437	Intuitive-01527453	
188	DX1766.186	Sales and Service Agreement between Intuitive Surgical, Inc. and Scott and White Memorial Hospital and Scott, Sherwood and Brindley Foundation	12/21/2004	Intuitive-01527614	Intuitive-01527630	
189	DX1766.187	Sales and Service Agreement between Intuitive Surgical and Health Care Finance and Construction Corporation	12/22/2004	Intuitive-01291728	Intuitive-01291744	
190	DX1766.188	Amendment between Catholic Health System and Intuitive Surgical	12/23/2004	Intuitive-01282331	Intuitive-01282342	
191	DX1766.189	Sales and Service Agreement between Intuitive Surgical, Inc. and Bellin Memorial Hospital, Inc.	12/23/2004	Intuitive-01526968	Intuitive-01526982	
192	DX1766.190	Sales and Service Agreement between Intuitive Surgical, Inc. and Century City Doctors Hospital, L.P.	12/23/2004	Intuitive-01527002	Intuitive-01527018	
193	DX1766.191	Sales and Service Agreement between Intuitive Surgical, Inc. and Mercy Hospital of Buffalo, Inc.	12/23/2004	Intuitive-01527390	Intuitive-01527404	
194	DX1766.192	Sales and Service Agreement between Intuitive Surgical, Inc. and Ochsner Clinic Foundation on behalf of Ochsner Clinic, LLC	12/27/2004	Intuitive-01527507	Intuitive-01527523	
195	DX1766.193	Sales and Service Agreement between Intuitive Surgical and Carilion Health System	12/30/2004	Intuitive-01524891	Intuitive-01524913	
196	DX1766.194	Sales and Service Agreement between Intuitive Surgical, Inc. and Loma Linda University Medical Center	12/30/2004	Intuitive-01527353	Intuitive-01527368	

Compilation of Select Intuitive Customer Contracts.					
Def.'s Temporary Exhibit No.	Description	Date	Beg Bates	End Bates	Objections
DX1767.01	Sales and Service Agreement between Intuitive Surgical and Duke University Medical Center	10/23/2001	Intuitive-01524994	Intuitive-01525016	
DX1767.02	Amendment Number 1 to the Sales and Service Agreement between Intuitive Surgical and The Johns Hopkins Hospital	1/5/2005	Intuitive-01291218	Intuitive-01291218	
DX1767.03	Amendment Number 1 to the Sales and Service Agreement between Intuitive Surgical and Duke University Medical Center	2/16/2005	Intuitive-02015961	Intuitive-02015961	
DX1767.04	Amendment Number 1 to the Sales and Service Agreement between	3/10/2005	Intuitive-02016090	Intuitive-02016090	
DX1767.05	Sales and Service Agreement between Intuitive Surgical and	03/30/2005	Intuitive-01527990	Intuitive-01528006	
DX1767.06	Master Purchase and Master Service Agreement between Intuitive Surgical and Beth Israel Medical Center	04/04/2005	Intuitive-01524447	Intuitive-01524476	
DX1767.07	Amendment Number 1 to the Master Purchase and Master Service Agreement between Intuitive Surgical and Beth Israel Medical Center	04/04/2005	Intuitive-01291328	Intuitive-01291328	
DX1767.08	Amendment Number 1 to the Sales and Service Agreement between Intuitive Surgical and Providence Health System-Oregon doing business as Providence St. Vincent Medical Center	4/8/2005	Intuitive-01291279	Intuitive-01291279	
DX1767.09	Sales Agreement between Intuitive Surgical and Northside Hospital	5/4/2005	Intuitive-02005750	Intuitive-02005771	
DX1767.10	Sales and Service Agreement between Intuitive Surgical and Providence Health System-Washington dba Providence Alaska Medical Center	6/10/2005	Intuitive-01529419	Intuitive-01529434	
DX1767.11	Amendment to the Sales and Service Agreement between Intuitive Surgical and Advocate Health and Hospitals Corporation dba Advocate Christ Medical Center	09/02/2005	Intuitive-02016095	Intuitive-02016096	
DX1767.12	Sales and Service Agreement between Intuitive Surgical and Pomona Valley Hospital Medical Center	9/30/2005	Intuitive-01529401	Intuitive-01529417	
DX1767.13	Sales and Service Agreement between Intuitive Surgical and Advocate Health and Hospitals Corporation dba Advocate Good Shepherd Hospital	10/28/2005	Intuitive-01527973	Intuitive-01527989	
DX1767.14	Sales and Service Agreement between Intuitive Surgical and Newark Beth Israel Medical Center	03/22/2006	Intuitive-01531860	Intuitive-01531875	
DX1767.15	Sales and Service Agreement between Intuitive Surgical and Providence Health Care, a Washington Nonprofit Corporation, d/b/a Sacred Heart Medical Center	3/29/2006	Intuitive-01532352	Intuitive-01532372	
DX1767.16	Sales and Service Agreement between Intuitive Surgical and Lahey Clinic Foundation Inc.	06/15/2006	Intuitive-01531253	Intuitive-01531268	
DX1767.17	Sales and Service Agreement between Intuitive Surgical and Providence Health System Southern California d/b/a Little Company of Mary Hospital	6/30/2006	Intuitive-01531330	Intuitive-01531344	
DX1767.18	First Amendment to Terms and Conditions of Purchase of Robotic Surgical Equipment Agreement between Intuitive Surgical and Banner Health	09/18/2006	Intuitive-01266395	Intuitive-01266398	
DX1767.19	Sales and Service Agreement between Intuitive Surgical and The Mayo Clinic	11/8/2006	Intuitive-01531501	Intuitive-01531534	
DX1767.20	Amendment to the Sales and Service Agreement between Intuitive Surgical and Johns Hopkins Hospital	12/1/2006	Intuitive-01266985	Intuitive-01266985	
DX1767.21	Sales and Service Agreement between Intuitive Surgical and Mayo Clinic Hospital	12/5/2006	Intuitive-01531439	Intuitive-01531469	
DX1767.22	Sales and Service Agreement between Intuitive Surgical and Advocate Health and Hospitals Corporation dba Advocate Lutheran General Hospital	12/19/2006	Intuitive-01530288	Intuitive-01530307	
DX1767.23	Sales Agreement between Intuitive Surgical and Duke University Health System	12/20/2006	Intuitive-01615627	Intuitive-01615648	
DX1767.24	Amendment to the Sales and Service Agreement between Intuitive Surgical and the Mayo Clinic	1/24/2007	Intuitive-01525626	Intuitive-01525626	
DX1767.25	Sales and Service Agreement between Intuitive Surgical and Regents of the University of Michigan	2/14/2007	Intuitive-01537818	Intuitive-01537837	
DX1767.26	Amendment No. 1 to the Sales and Service Agreement UM --021307 between Intuitive Surgical and Regents of the University of Michigan	2/27/2007	Intuitive-01269231	Intuitive-01269234	
DX1767.27	Sales and Service Agreement between Intuitive Surgical and University of Illinois at Chicago	4/23/2007	Intuitive-01306760	Intuitive-01306776	
DX1767.28	Sales Agreement between Intuitive Surgical and Northside Hospital	5/3/2007	Intuitive-01615248	Intuitive-01615268	
DX1767.29	Sales and Service Agreement for the Purchase of the da Vinci Surgical System between Intuitive Surgical and Kaiser Foundation Health Plan	7/10/2007	Intuitive-01536382	Intuitive-01536400	
DX1767.30	Master Agreement for the Sale and Service of the da Vinci Surgical System between Intuitive Surgical and Kaiser Foundation Health Plan Inc	7/17/2007	Intuitive-01274522	Intuitive-01274543	
DX1767.31	Sales and Service Agreement for the Purchase of the da Vinci Surgical System with High Definition Vision between Intuitive Surgical and Winchester Hospital	08/21/2007	Intuitive-01539526	Intuitive-01539543	
DX1767.32	Purchase and License Agreement between Intuitive Surgical and Northwestern Memorial Healthcare on behalf of Northwestern Memorial Healthcare	8/29/2007	Intuitive-01537281	Intuitive-01537299	
DX1767.33	Sales and Service Agreement between Intuitive Surgical and SSM Health Care of Wisconsin, Inc., owning and operating St. Mary's Hospital Medical Center	9/5/2007	Intuitive-01349816	Intuitive-01349832	

DX1767.34	Sales and Service Agreement for the Purchase of the <i>da Vinci</i> Surgical System with High Definition between Intuitive Surgical and Advocate Illinois Masonic Medical Center	09/13/2007	Intuitive-01533644	Intuitive-01533660	
DX1767.35	Sales and Service Agreement for the Purchase of the <i>da Vinci</i> Surgical System with High Definition Vision between Intuitive Surgical and Lahey Clinic Foundation	09/14/2007	Intuitive-01536454	Intuitive-01536470	
DX1767.36	Sales and Service Agreement between Intuitive Surgical and Marin General Hospital	9/28/2007	Intuitive-01536645	Intuitive-01536667	
DX1767.37	Sales and Service Agreement between Intuitive Surgical and The Mayo Clinic	12/14/2007	Intuitive-01536741	Intuitive-01536758	
DX1767.38	Sales and Service Agreement between Intuitive Surgical and Clarian Health Partners Inc - Indiana University Hospital	1/18/2008	Intuitive-01281894	Intuitive-01281909	
DX1767.39	Sales Agreement between Intuitive Surgical and Duke University Health System	2/14/2008	Intuitive-01612971	Intuitive-01612997	
DX1767.40	Sales and Service Agreement between Intuitive Surgical and The Board of Trustees of the University of Illinois on behalf of the University of Illinois at Chicago	2/22/2008	Intuitive-01306811	Intuitive-01306827	
DX1767.41	Second Amendment to Terms and Conditions of Purchase of Robotic Surgical Equipment Agreement between Intuitive Surgical and Banner Health	03/05/2008	Intuitive-01282263	Intuitive-01282268	
DX1767.42	Sales Agreement between Intuitive Surgical and Duke University Health System	3/19/2008	Intuitive-01612944	Intuitive-01612970	
DX1767.43	Sales Agreement between Intuitive Surgical and Northside Hospital	6/18/2008	Intuitive-01615345	Intuitive-01615366	
DX1767.44	Sales and Service Agreement between Intuitive Surgical and Northeast Georgia Medical Center	6/27/2008	Intuitive-01552433	Intuitive-01552449	
DX1767.45	Sales and Service Agreement for the Purchase of the <i>da Vinci</i> Surgical System with High Definition Vision between Intuitive Surgical and Kaiser Foundation Hospitals	7/14/2008	Intuitive-01548248	Intuitive-01548267	
DX1767.46	Sales and Service Agreement for the Purchase of the <i>da Vinci</i> Surgical System with High Definition Vision between Intuitive Surgical and Advocate Health and Hospitals dba Advocate Lutheran General Hospital	08/21/2008	Intuitive-01548924	Intuitive-01548944	
DX1767.47	Sales and Service Agreement for the Purchase of the <i>da Vinci</i> Surgical System with High Definition Vision between Intuitive Surgical and Advocate Health and Hospitals dba Good Shepherd Hospital	08/22/2008	Intuitive-01549123	Intuitive-01549145	
DX1767.48	Third Amendment to Terms and Conditions of Purchase of Robotic Surgical Equipment Agreement between Intuitive Surgical and Banner Health	09/24/2008	Intuitive-01292117	Intuitive-01292118	
DX1767.49	Sales and Service Agreement for the Purchase of the <i>da Vinci</i> Surgical System with High Definition Vision between Intuitive Surgical and Seton Medical Center	09/26/2008	Intuitive-01548706	Intuitive-01548722	
DX1767.50	Sales and Service Agreement between Intuitive Surgical and Salinas Valley Memorial Hospital	9/26/2008	Intuitive-01548688	Intuitive-01548704	
DX1767.51	Sales and Service Agreement between Intuitive Surgical and Conway Regional Medical Center, Inc. d/b/a Conway Regional Health System	9/30/2008	Intuitive-00518232	Intuitive-00518248	
DX1767.52	Amendment 1 to the Sales and Service Agreement Between Intuitive Surgical Inc and Northeast Georgia Medical Center	11/12/2008	Intuitive-01293634	Intuitive-01293634	
DX1767.53	Sales and Service Agreement between Intuitive Surgical and The Mayo Clinic	11/19/2008	Intuitive-01551359	Intuitive-01551376	
DX1767.54	Amendment No.1 to the Sales and Service Agreement between Intuitive Surgical and The Mayo Clinic	11/20/2008	Intuitive-02017519	Intuitive-02017519	
DX1767.55	Sales, License, and Service Agreement between Intuitive Surgical and Beth Israel Deaconess Medical Center	12/22/2008	Intuitive-01420901	Intuitive-01420920	
DX1767.56	Sales, License, and Service Agreement between Intuitive Surgical and Beth Israel Deaconess Medical Center	12/23/2008	Intuitive-01420921	Intuitive-01420940	
DX1767.57	Sales and Service Agreement between Intuitive Surgical and Legacy Health System for its Salmon Creek Hospital	3/16/2009	Intuitive-01555678	Intuitive-01555695	
DX1767.58	Sales, License and Service Agreement between Intuitive Surgical and Public Hospital District No. 1 of King County, d/b/a Valley Medical Center	3/25/2009	Intuitive-01261022	Intuitive-01261038	
DX1767.59	Sales, License, and Service Agreement between Intuitive Surgical and Northside Hospital	3/31/2009	Intuitive-01295736	Intuitive-01295750	
DX1767.60	Addendum to the Sales and Service Agreement between Intuitive Surgical and Legacy Health System for Salmon Creek Hospital	4/29/2009	Intuitive-01296296	Intuitive-01296299	
DX1767.61	Sales, License and Service Agreement for the Purchase of the <i>da Vinci</i> Surgical System between Intuitive Surgical and Kaiser Foundation Hospitals	6/22/2009	Intuitive-01298745	Intuitive-01298763	
DX1767.62	Sales, License, and Service Agreement between Intuitive Surgical and Seton Healthcare dba Seton Medical Center Williamson	06/29/2009	Intuitive-01298937	Intuitive-01298955	
DX1767.63	Amendment to the Sales and Service Agreement between Intuitive Surgical and Advocate Health Care	8/13/2009	Intuitive-02020827	Intuitive-02020827	
DX1767.64	Sales, License and Service Agreement between Intuitive Surgical and Providence Health Care, a Washington Nonprofit Corporation, d/b/a Providence Sacred Heart Medical Center	9/28/2009	Intuitive-01421484	Intuitive-01421501	
DX1767.65	Sales, License and Service Agreement between Intuitive Surgical and SSM Health Care St. Louis owning and operating SSM Health Care St. Louis	11/4/2009	Intuitive-01576584	Intuitive-01576598	
DX1767.66	Banner Health Fourth Amendment to terms and Conditions of Purchase of Robotic Surgical Equipment Agreement	11/23/2009	Intuitive-01300335	Intuitive-01300338	

DX1767.67	Sales, License and Service Agreement between Intuitive Surgical and King County Public Hospital District No. 2, d/b/a Evergreen Healthcare	11/25/2009	Intuitive-01260726	Intuitive-01260758	
DX1767.68	Sales, License and Service Agreement between Intuitive Surgical and Piedmont Healthcare, Inc. on behalf of Piedmont Fayette Hospital and Piedmont Hospital	12/3/2009	Intuitive-01303858	Intuitive-01303875	
DX1767.69	Sales, License, and Service Agreement between Intuitive Surgical and Seton dba Baptist Hospital	12/07/2009	Intuitive-01575747	Intuitive-01575761	
DX1767.70	Amendment 1 to the Agreement between Intuitive Surgical and Seton dba Baptist Hospital	12/07/2009	Intuitive-02017030	Intuitive-02017031	
DX1767.71	Sales, License and Service Agreement between Intuitive Surgical and Mayo Clinic	12/18/2009	Intuitive-01573847	Intuitive-01573860	
DX1767.72	Amendment to the Sales and Service Agreement between Intuitive Surgical and Legacy Health System for its Good Samaritan Hospital	12/22/2009	Intuitive-01575838	Intuitive-01575838	
DX1767.73	Banner Health Fifth Amendment to terms and Conditions of Purchase of Robotic Surgical Equipment Agreement	12/22/2009	Intuitive-01303832	Intuitive-01303837	
DX1767.74	Seton Medical Center Austin Addendum to the da Vinci Surgical System with Dual Console Sales, License, and Service Agreement between Intuitive Surgical and Seton Healthcare dba Seton Medical Center Austin	02/23/2010	Intuitive-01581946	Intuitive-01581949	
DX1767.75	Sales, License and Service Agreement between Intuitive Surgical and Legacy Health System for its Emanuel Medical Center	3/16/2010	Intuitive-01582401	Intuitive-01582417	
DX1767.76	Sales, License, and Service Agreement between Intuitive Surgical and Regents of the University of Michigan	3/17/2010	Intuitive-01308750	Intuitive-01308760	
DX1767.77	Amendment to the Sales and Service Agreement between Intuitive Surgical and Regents of the University of Michigan	3/17/2010	Intuitive-01308772	Intuitive-01308772	
DX1767.78	Sales, License and Service Agreement between Intuitive Surgical and Kaiser Permanente Medical Center	3/22/2010	Intuitive-01581530	Intuitive-01581548	
DX1767.79	Sales, License, and Service Agreement between Intuitive Surgical and Mount Auburn Hospital	04/12/2010	Intuitive-01586171	Intuitive-01586182	
DX1767.80	Amendment 2 to the Sales and Service Agreement between Intuitive Surgical and The Board of Trustees of the University of Illinois on behalf of the University of Illinois at Chicago	4/30/2010	Intuitive-01311880	Intuitive-01311893	
DX1767.81	Sales, License and Service Agreement between Intuitive Surgical and Johns Hopkins Bayview Medical Center	6/29/2010	Intuitive-01317777	Intuitive-01317796	
DX1767.82	Sales, License, and Service Agreement between Intuitive Surgical and Lovelace Health System dba Lovelace Medical Center	10/22/2010	Intuitive-01585851	Intuitive-01585864	
DX1767.83	Service Agreement between Intuitive Surgical and Mayo Clinic	11/23/2010	Intuitive-01585602	Intuitive-01585607	
DX1767.84	Sales and License Agreement between Intuitive Surgical and Mayo Clinic	11/23/2010	Intuitive-01585717	Intuitive-01585735	
DX1767.85	Master Lease Agreement between Intuitive Surgical and Kaiser Foundation Health Plan	12/7/2010	Intuitive-02034310	Intuitive-02034343	
DX1767.86	Sales, License, and Service Agreement between Intuitive Surgical and Beth Israel Medical Center	12/15/2010	Intuitive-01586236	Intuitive-01586246	
DX1767.87	Amendment No. 1 to the Sales, License and Service Agreement between Intuitive Surgical and Regents of the University of Michigan	12/15/2010	Intuitive-01586316	Intuitive-01586318	
DX1767.88	Sales, License, and Service Agreement between Intuitive Surgical and Mayo Clinic	1/6/2011	Intuitive-01586704	Intuitive-01586710	
DX1767.89	Sales and Service Agreement between Intuitive Surgical and Advocate Health and Hospitals dba Advocate Christ Medical Center	02/01/2011	Intuitive-01524861	Intuitive-01524887	
DX1767.90	Sales, License and Service Agreement between Intuitive Surgical and Legacy Health on behalf of Legacy Mount Hood Medical Center	3/21/2011	Intuitive-01586608	Intuitive-01586627	
DX1767.91	Amendment No. 1 to Sales and Service Agreement between Intuitive Surgical and SSM Health Care of Wisconsin, Inc., owning and operating St. Mary's Hospital	3/28/2011	Intuitive-01587217	Intuitive-01587219	
DX1767.92	Addendum to the Sales, License and Service Agreement between Intuitive Surgical and Legacy Health on behalf of Legacy Mount Hood Medical Center	3/31/2011	Intuitive-01352025	Intuitive-01352025	
DX1767.93	Sales and Service Agreement between Intuitive Surgical and Advocate Health and Hospitals dba Advocate Lutheran General Hospital	05/17/2011	Intuitive-01437180	Intuitive-01437200	
DX1767.94	Sales and Service Agreement between Intuitive Surgical and Advocate Health and Hospitals Corporation dba Advocate Christ Medical Center	05/17/2011	Intuitive-01587457	Intuitive-01587477	
DX1767.95	Sales and Service Agreement between Intuitive Surgical and Advocate Health and Hospitals Corporation dba Advocate Lutheran General Hospital	05/17/2011	Intuitive-01587478	Intuitive-01587498	
DX1767.96	Service Agreement between Intuitive Surgical and Luther Midelfort Hospital - Mayo Health System	7/8/2011	Intuitive-01590680	Intuitive-01590686	
DX1767.97	Sales, License, and Service Agreement between Intuitive Surgical and Mayo Clinic Health System - Eau Claire Hospital	7/21/2011	Intuitive-01590963	Intuitive-01590969	
DX1767.98	Service Agreement between Intuitive Surgical and Mayo Clinic Health System Mankato	8/2/2011	Intuitive-01590692	Intuitive-01590697	
DX1767.99	Amendment to the Sales, License & Service Agreement between Intuitive Surgical and Northside Hospital	9/12/2011	Intuitive-01590475	Intuitive-01590482	
DX1767.100	Amendment to the Sales, License and Service Agreement between Intuitive Surgical and Northside Hospital	9/13/2011	Intuitive-02018587	Intuitive-02018588	
DX1767.101	Amendment to the Master Agreement for Sales between Intuitive Surgical and Duke University and Duke University Health System	9/28/2011	Intuitive-01612438	Intuitive-01612444	
DX1767.102	Amendment to the Service Agreement between Intuitive Surgical and Duke University and Duke University Health System	9/30/2011	Intuitive-01599617	Intuitive-01599618	

DX1767.103	Amendment 1 to the Sales and Service Agreement between Intuitive Surgical and Duke University Medical Center	10/24/2011	Intuitive-02015960	Intuitive-02015960	
DX1767.104	Banner Health Eleventh Amendment to terms and Conditions of Purchase of Robotic Surgical Equipment Agreement	10/27/2011	Intuitive-01591423	Intuitive-01591427	
DX1767.105	Sales, License, and Service Agreement between Intuitive Surgical and Pullman Regional Hospital	11/9/2011	Intuitive-01594302	Intuitive-01594317	
DX1767.106	Service Agreement between Intuitive Surgical and Mayo Clinic	11/17/2011	Intuitive-01593615	Intuitive-01593620	
DX1767.107	Sales, License, and Service Agreement between Intuitive Surgical and Pomona Valley Hospital Medical Center	12/12/2011	Intuitive-01594173	Intuitive-01594186	
DX1767.108	Sales, License, and Service Agreement between Intuitive Surgical and Lovelace Health System dba Lovelace Medical Center	12/14/2011	Intuitive-00159262	Intuitive-00159281	
DX1767.109	Sales, License, and Service Agreement between Intuitive Surgical and Hillcrest Healthcare System	12/14/2011	Intuitive-01260465	Intuitive-01260480	
DX1767.110	Amendment No. 3 to Sales and Service Agreement between Intuitive Surgical and the Board of Trustees of the University of Illinois on behalf of the University of Illinois at Chicago	12/14/2011	Intuitive-01594905	Intuitive-01594910	
DX1767.111	Amendment 1 to the Sales, License and Service Agreement between Intuitive Surgical and Piedmont Healthcare, Inc.	12/15/2011	Intuitive-01593428	Intuitive-01593432	
DX1767.112	Sales, License and Service Agreement between Intuitive Surgical and Legacy Health on behalf of Legacy Meridian Park Medical Center	12/15/2011	Intuitive-01594133	Intuitive-01594152	
DX1767.113	Amendment 1 to the Sales, License and Service Agreement between Intuitive Surgical and Providence Health Care, a Washington Nonprofit Corporation d/b/a Providence Sacred Heart Medical Center	12/23/2011	Intuitive-01420779	Intuitive-01420782	
DX1767.114	Amendment 1 to the Sales, License, and Service Agreement between Intuitive Surgical and Beth Israel Deaconess Medical Center	12/27/2011	Intuitive-01595122	Intuitive-01595127	
DX1767.115	Sales, License and Service Agreement between Intuitive Surgical and Kaiser Permanente Medical Center	1/6/2012	Intuitive-01595866	Intuitive-01595886	
DX1767.116	Franciscan Alliance Amendment No. 2 to the SLA	2/27/2012	Intuitive-01260971	Intuitive-01260976	
DX1767.117	Amendment 1 to the Sales, License and Service Agreement between Intuitive Surgical and Kaiser Permanente Medical Center	3/5/2012	Intuitive-01428212	Intuitive-01428216	
DX1767.118	Use, License & Service Agreement between Intuitive Surgical and Franciscan Health Crown Point	3/7/2012	Intuitive-01240524	Intuitive-01240535	
DX1767.119	Amendment No. 1 to Sales and Service Agreement between Intuitive Surgical and Indiana University Health	3/14/2012	Intuitive-01595320	Intuitive-01595328	
DX1767.120	Sales, License, and Service Agreement between Intuitive Surgical and King County Public Hospital District No. 2, d/b/a Evergreen Healthcare	3/20/2012	Intuitive-01260759	Intuitive-01260773	
DX1767.121	Amendment to the Sales, License & Service Agreement between Intuitive Surgical and Northside Hospital	3/21/2012	Intuitive-01595539	Intuitive-01595547	
DX1767.122	Sales, License, and Service Agreement between Intuitive and Kaiser Permanente Medical Center	4/2/2012	Intuitive-01260599	Intuitive-01260619	
DX1767.123	Amendment 1 to the Sales, License, and Service Agreement between Intuitive Surgical and Advocate Health and Hospitals Corporation dba Advocate Lutheran General Hospital	05/01/2012	Intuitive-02019459	Intuitive-02019470	
DX1767.124	Sales, License, and Service Agreement between Mayo Clinic Health System - Franciscan Medical Center	5/31/2012	Intuitive-01260547	Intuitive-01260569	
DX1767.125	Amendment 2 to the Sales, License and Service Agreement between Intuitive Surgical and Piedmont Healthcare, Inc.	9/28/2012	Intuitive-01597761	Intuitive-01597764	
DX1767.126	Amendment to the Sales, License and Service Agreement between Intuitive Surgical and IU Health North Hospital formerly known as Clarion Health Partners Inc - Indiana University Hospital	10/8/2012	Intuitive-01599181	Intuitive-01599184	
DX1767.127	Sales, License and Service Agreement between Intuitive Surgical and Kaiser Permanente Medical Center	10/25/2012	Intuitive-01599197	Intuitive-01599215	
DX1767.128	Sales and Service Agreement between Intuitive Surgical and Advocate Health and Hospitals Corporation dba Advocate Good Shepherd Hospital	12/07/2012	Intuitive-01598366	Intuitive-01598386	
DX1767.129	Sales and Service Agreement between Intuitive Surgical and Advocate Health and Hospitals Corporation dba Advocate South Suburban Hospital	12/08/2012	Intuitive-01598387	Intuitive-01598406	
DX1767.130	Sales and Service Agreement between Intuitive Surgical and Advocate Health and Hospitals Corporation dba Advocate Illinois Masonic Medical Center	12/19/2012	Intuitive-01598346	Intuitive-01598365	
DX1767.131	Amendment 2 to the Master Agreement for Sales and Service between Intuitive Surgical and Duke University & Duke University Health System	12/20/2012	Intuitive-01598410	Intuitive-01598417	
DX1767.132	Amendment 3 to the Master Agreement for Sales and Service between Duke University and Duke University Health System	12/20/2012	Intuitive-01598990	Intuitive-01598997	
DX1767.133	Amendment 4 to the Master Agreement for Sales and Service between Duke University and Duke University Health System	12/20/2012	Intuitive-01598998	Intuitive-01599005	
DX1767.134	Amendment 5 to the Master Agreement for Sales and Service between Duke University and Duke University Health System	12/20/2012	Intuitive-01599006	Intuitive-01599010	
DX1767.135	Amendment 6 to the Master Agreement for Sales and Service between Duke University and Duke University Health System	12/20/2012	Intuitive-01599011	Intuitive-01599015	
DX1767.136	Banner Health Twelfth Amendment to terms and Conditions of Purchase of Robotic Surgical Equipment Agreement	12/20/2012	Intuitive-01495630	Intuitive-01495639	
DX1767.137	Sales and Service Agreement between Intuitive Surgical and Advocate Health and Hospitals Corporation dba Advocate Condell Medical Center	12/21/2012	Intuitive-01598326	Intuitive-01598345	
DX1767.138	Sales, License and Service Agreement between Intuitive Surgical and Kaiser Foundation Health Plan of Northwest	2/21/2013	Intuitive-01600170	Intuitive-01600190	

DX1767.139	Sales, License, and Service Agreement between Intuitive Surgical and Marin General Hospital	3/1/2013	Intuitive-01600811	Intuitive-01600822	
DX1767.140	Sales, License and Service Agreement between Intuitive Surgical and Northwestern Memorial Healthcare	3/14/2013	Intuitive-01506848	Intuitive-01506860	
DX1767.141	Amendment to the Sales, License and Service Agreement between Intuitive Surgical and IU Health	3/19/2013	Intuitive-01600264	Intuitive-01600270	
DX1767.142	Sales, License and Service Agreement between Intuitive Surgical and Providence Health & Services-Washington dba Providence Sacred Heart Medical Center	3/26/2013	Intuitive-01600583	Intuitive-01600600	
DX1767.143	Sales, License and Service Agreement between Providence Health System-Southern California dba Providence Saint Joseph Medical Center	3/26/2013	Intuitive-01600919	Intuitive-01600936	
DX1767.144	Sales, License and Service Agreement between Intuitive Surgical and Providence Health & Services-Montana dba St. Patrick Hospital	3/26/2013	Intuitive-01600937	Intuitive-01600954	
DX1767.145	Sales, License and Service Agreement between Intuitive Surgical and Kaiser Permanente Medical Center	5/29/2013	Intuitive-01604777	Intuitive-01604797	
DX1767.146	Sales, License and Service Agreement between Intuitive Surgical and Kaiser Permanente Medical Center	8/5/2013	Intuitive-01618040	Intuitive-01618063	
DX1767.147	Amendment to the Sales, License and Service Agreement between Intuitive Surgical and Northside Hospital	9/20/2013	Intuitive-01621370	Intuitive-01621375	
DX1767.148	Amendment 2 to the Sales, License, and Service Agreement between Intuitive Surgical and Advocate Health and Hospitals Corporation dba Advocate Lutheran General Hospital	11/22/2013	Intuitive-01634980	Intuitive-01634984	
DX1767.149	Amendment 2 to the Sales, License, and Service Agreement between Intuitive Surgical and Beth Israel Deaconess Medical Center Inc.	12/09/2013	Intuitive-01636107	Intuitive-01636114	
DX1767.150	Sales, License, and Service Agreement between Intuitive Surgical and Northeast Georgia Medical Center	12/19/2013	Intuitive-01636942	Intuitive-01636953	
DX1767.151	Sales, License, and Service Agreement between Intuitive Surgical and Northeast Georgia Medical Center	12/19/2013	Intuitive-02021148	Intuitive-02021159	
DX1767.152	Sales, License, and Service Agreement between Intuitive Surgical and Crescent City Surgical Center Operating Company, LLC	12/24/2013	Intuitive-00518249	Intuitive-00518259	
DX1767.153	Use, License, and Service Agreement between Intuitive Surgical and Providence Health System - Southern California d/b/a Providence Holy Cross Medical Center	3/24/2014	Intuitive-01641266	Intuitive-01641277	
DX1767.154	Lease Agreement between Intuitive Surgical and Providence Health System - Southern California d/b/a Providence Holy Cross Medical Center	3/25/2014	Intuitive-01641259	Intuitive-01641265	
DX1767.155	Amendment to the Sales, License and Service Agreement between Intuitive Surgical and Legacy Health	5/16/2014	Intuitive-01642269	Intuitive-01642269	
DX1767.156	Use, License, and Service Agreement between Intuitive Surgical and Keck Hospital of USC	6/25/2014	Intuitive-01644776	Intuitive-01644786	
DX1767.157	Amendment to the Sales, and Service Agreement between Intuitive Surgical and Conway Regional Medical Center	8/26/2014	Intuitive-00518226	Intuitive-00518231	
DX1767.158	Amendment to the Sales, License and Service Agreement between Intuitive Surgical and IU Health	10/22/2014	Intuitive-01650366	Intuitive-01650375	
DX1767.159	Sales, License and Service Agreement between Intuitive Surgical and Kaiser Permanente Walnut Creek Medical Center	11/5/2014	Intuitive-01652385	Intuitive-01652404	
DX1767.160	Lease Agreement between Intuitive Surgical and AMISUB of South Carolina, Inc. For the benefit of Piedmont Healthcare System	11/19/2014	Intuitive-01651560	Intuitive-01651563	
DX1767.161	Use, License, and Service Agreement between Intuitive Surgical and AMISUB of South Carolina, Inc., for the benefit of Piedmont Healthcare System	11/19/2014	Intuitive-01651564	Intuitive-01651576	
DX1767.162	Amendment Number 1 to the Sales, License and Service Agreement between Intuitive Surgical and Kaiser Permanente Walnut Creek Medical Center	12/5/2014	Intuitive-01652792	Intuitive-01652793	
DX1767.163	Banner Health Fourteenth Amendment to terms and Conditions of Purchase of Robotic Surgical Equipment Agreement	12/19/2014	Intuitive-01653105	Intuitive-01653111	
DX1767.164	Amendment 1 to the Sales, License & Service Agreement between Intuitive Surgical and Northside Hospital	2/12/2015	Intuitive-01662775	Intuitive-01662778	
DX1767.165	Sales and Service Agreement between Intuitive Surgical and Advocate Health and Hospitals Corporation dba Good Samaritan Hospital	03/11/2015	Intuitive-02006153	Intuitive-02006175	
DX1767.166	Amendment 2 to the Sales, License and Service Agreement between Intuitive Surgical and Northwest Georgia Medical Center	3/12/2015	Intuitive-01663914	Intuitive-01663917	
DX1767.167	Amendment 1 to the Sales, License and Service Agreement between Intuitive Surgical and Northeast Georgia Medical Center	3/25/2015	Intuitive-01663918	Intuitive-01663922	
DX1767.168	Amendment to the Sales, License and Service Agreement between Intuitive Surgical and Kaiser Foundation Hospitals on behalf of Kaiser Permanente San Francisco Medical Center	3/27/2015	Intuitive-01663750	Intuitive-01663757	
DX1767.169	Amendment 3 to the Sales, License and Service Agreement between Intuitive Surgical and Northeast Georgia Medical Center	4/21/2015	Intuitive-01668960	Intuitive-01668963	
DX1767.170	Sales, License, and Service Agreement between Intuitive Surgical and Honor Health Scottsdale Osborn Medical Center	5/1/2015	Intuitive-02005587	Intuitive-02005599	
DX1767.171	Amendment No. 3 to Sales, License and Service Agreement between Intuitive Surgical and Regents of the University of Michigan	6/10/2015	Intuitive-01666805	Intuitive-01666807	
DX1767.172	Franciscan Alliance Amendment to the SLA	6/17/2015	Intuitive-01260516	Intuitive-01260521	
DX1767.173	Amendment to the Sales, License and Service Agreement between Intuitive Surgical and Northwestern Memorial Healthcare	6/19/2015	Intuitive-01667901	Intuitive-01667904	
DX1767.174	Amendment 2 to the Sales, License and Service Agreement between Intuitive Surgical and The Johns Hopkins Hospital	6/26/2015	Intuitive-00614921	Intuitive-00614921.0010	

DX1767.175	Amendment to the Sales Agreement and Services Agreement between Intuitive Surgical and Duke University Health System	7/14/2015	Intuitive-01669566	Intuitive-01669570	
DX1767.176	Amendment to the Sales, License and Service Agreement between Intuitive Surgical and Northside Hospital	9/17/2015	Intuitive-01673235	Intuitive-01673247	
DX1767.177	Sales, License, and Service Agreement between Intuitive Surgical and Universal Health Services on behalf of Northern Nevada Medical Center	10/28/2015	Intuitive-01676371	Intuitive-01676382	
DX1767.178	Sales, License and Service Agreement between Intuitive Surgical and Legacy Health on behalf of Legacy Salmon Creek	12/8/2015	Intuitive-01679278	Intuitive-01679289	
DX1767.179	Use, License & Service Agreement between Intuitive Surgical and Salinas Valley Memorial Healthcare System	12/10/2015	Intuitive-01681409	Intuitive-01681427	
DX1767.180	Sales and Service Agreement between Intuitive Surgical and Advocate Health and Hospitals Corporation dba Advocate Sherman Hospital	12/15/2015	Intuitive-01679612	Intuitive-01679631	
DX1767.181	Sales, License, and Service Agreement between Intuitive Surgical and the University of Illinois Hospital and Health Sciences System	12/17/2015	Intuitive-00099486	Intuitive-00099499	
DX1767.182	Amendment 2 to the Sales and Service Agreement between Intuitive Surgical and Northwestern Memorial Healthcare	12/17/2015	Intuitive-01680115	Intuitive-01680119	
DX1767.183	Amendment to the Sales, License and Service Agreement between Intuitive Surgical and Mayo Clinic	12/21/2015	Intuitive-01681074	Intuitive-01681077	
DX1767.184	Amendment 3 to the Sales, License and Service Agreement between Intuitive Surgical and Johns Hopkins Bayview Medical Center	12/22/2015	Intuitive-00614920	Intuitive-00614920.0006	
DX1767.185	Sales, License, and Service Agreement between Intuitive Surgical and Winchester Medical Center	12/23/2015	Intuitive-01681474	Intuitive-01681486	
DX1767.186	Amendment to the Use, License and Service Agreement & Lease Agreement between Intuitive Surgical and Salinas Valley Memorial Healthcare System	12/31/2015	Intuitive-01682776	Intuitive-01682777	
DX1767.187	Use, License, and Service Agreement between Intuitive Surgical and Lahey Clinic	02/29/2016	Intuitive-01684779	Intuitive-01684800	
DX1767.188	Sales, License, and Service Agreement between Intuitive Surgical and Universal Health Services on behalf of Summerlin Hospital Medical Center	3/23/2016	Intuitive-01685895	Intuitive-01685906	
DX1767.189	Amendment 3 to the Sales, License and Service Agreement between Intuitive Surgical and Northwestern Memorial Healthcare	3/28/2016	Intuitive-01686411	Intuitive-01686419	
DX1767.190	Sales, License, and Service Agreement between Intuitive Surgical and Legacy Health on behalf of Legacy Emanuel Hospital and Health Center	3/30/2016	Intuitive-01687907	Intuitive-01687920	
DX1767.191	Banner Health Fifteenth Amendment to terms and Conditions of Purchase of Robotic Surgical Equipment Agreement	5/20/2016	Intuitive-01690072	Intuitive-01690076	
DX1767.192	Sales, License and Service Agreement between Intuitive Surgical and Kaiser Foundation Hospitals - San Diego Medical Center	7/27/2016	Intuitive-01694753	Intuitive-01694773	
DX1767.193	Sales, License, and Service Agreement between Intuitive Surgical and SSM-SLUH, Inc., a Missouri nonprofit corporation, d/b/a SSM Health Saint Louis University Hospital	8/15/2016	Intuitive-01697507	Intuitive-01697519	
DX1767.194	Sales, License, and Service Agreement between Intuitive Surgical and Conway Community Services d/b/a Baptist Health Medical Center - Conway	8/29/2016	Intuitive-01695405	Intuitive-01695417	
DX1767.195	Franciscan Alliance Amendment to the SLSA	9/13/2016	Intuitive-01253296	Intuitive-01253305	
DX1767.196	Amendment to the Sales and License Agreement and to the Service Agreement between Intuitive Surgical and Mayo Clinic	10/17/2016	Intuitive-01704677	Intuitive-01704682	
DX1767.197	Amendment to the Sales and License Agreement and to the Service Agreement between Intuitive Surgical and Mayo Clinic	11/15/2016	Intuitive-01704705	Intuitive-01704709	
DX1767.198	Amendment to the Sales and License Agreement and to the Service Agreement between Intuitive Surgical and Mayo Clinic	11/15/2016	Intuitive-01704800	Intuitive-01704805	
DX1767.199	Sales and License Agreement between Intuitive Surgical and Universal Health Services on behalf of Aiken Regional Medical Centers	12/21/2016	Intuitive-01707120	Intuitive-01707135	
DX1767.200	Sales, License, and Service Agreement between Intuitive Surgical and Universal Health Services on behalf of Desert Springs Hospital	12/21/2016	Intuitive-01708233	Intuitive-01708244	
DX1767.201	Amendment to the Sales, License, and Service Agreement between Intuitive Surgical and Advocate Health and Hospitals Corporation	12/22/2016	Intuitive-01707153	Intuitive-01707155	
DX1767.202	Sales, License, and Service Agreement between Intuitive Surgical and Piedmont Healthcare, Inc.	12/23/2016	Intuitive-00299311	Intuitive-00299326	
DX1767.203	Lease Agreement between Intuitive Surgical and Beth Israel Deaconess Hospital Milton	12/27/2016	Intuitive-01708557	Intuitive-01708576	
DX1767.204	Amendment 1 to the Sales, License and Service Agreement between Intuitive Surgical and Northside Hospital, Inc.	1/18/2017	Intuitive-01709362	Intuitive-01709367	
DX1767.205	Amendment Number 1 to the Lease Agreement between Intuitive Surgical and Piedmont Athens Regional Medical Center f/k/a Athens Regional Medical Center, Inc.	1/19/2017	Intuitive-01709360	Intuitive-01709361	
DX1767.206	Amendment to the Sales, License and Service Agreement between Intuitive Surgical and University of Illinois Hospital and Health Science System	2/7/2017	Intuitive-01711539	Intuitive-01711542	
DX1767.207	Franciscan Health Crown Point Lease Agreement	3/7/2017	Intuitive-01240518	Intuitive-01240523	
DX1767.208	Service Agreement between Intuitive Surgical and Providence St. Joseph Health	4/21/2017	Intuitive-00019174	Intuitive-00019180	
DX1767.209	Sales, License, and Service Agreement between Intuitive Surgical and Universal Health Services on behalf of Henderson Hospital	5/15/2017	Intuitive-00300051	Intuitive-00300062	
DX1767.210	Use, License & Service Agreement between Intuitive Surgical and CHI Franciscan Health on behalf of St. Joseph Medical Center	5/19/2017	Intuitive-00300071	Intuitive-00300093	
DX1767.211	Use, License & Service Agreement between Intuitive Surgical and Larken Community Hospital	6/9/2017	Intuitive-00300421	Intuitive-00300445	

DX1767.212	Sales, License and Service Agreement between Intuitive Surgical and Kaiser Foundation Hospitals - Oakland Medical Center	6/16/2017	Intuitive-01722041	Intuitive-01722061
DX1767.213	Banner Health Sixteenth Amendment to terms and Conditions of Purchase of Robotic Surgical Equipment Agreement	7/14/2017	Intuitive-01722308	Intuitive-01722313
DX1767.214	Banner Health Seventeenth Amendment to terms and Conditions of Purchase of Robotic Surgical Equipment Agreement	7/14/2017	Intuitive-01751728	Intuitive-01751732
DX1767.215	Amendment to the Sales, License, and Service Agreement between Intuitive Surgical and Lovelace Women's Hospital	07/21/2017	AHS_MGMT-INTUITIVE_0000201	AHS_MGMT-INTUITIVE_0000206
DX1767.216	Amendment to the Sales, License, and Service Agreement between Intuitive Surgical and Lovelace Health System dba Lovelace Women's Hospital	07/21/2017	Intuitive-01722215	Intuitive-01722220
DX1767.217	Banner Health Eighteenth Amendment to terms and Conditions of Purchase of Robotic Surgical Equipment Agreement	7/31/2017	Intuitive-01751723	Intuitive-01751727
DX1767.218	Lease Agreement between Intuitive Surgical and Providence Health & Services-Washington, dba Providence Sacred Heart Medical Center	9/1/2017	Intuitive-00301736	Intuitive-00301754
DX1767.219	Master Agreement for the Da Vinci Surgical System and Related Products and Services between Intuitive and Kaiser Foundation Health Plan	9/1/2017	Intuitive-01024554	Intuitive-01024608
DX1767.220	Service Agreement between Intuitive Surgical and Northwestern Memorial Healthcare	9/11/2017	Intuitive-00061183	Intuitive-00061190
DX1767.221	Use, License & Service Agreement between Intuitive Surgical and Providence Health System-Southern California d/b/a Providence Little Company of Mary Medical Center Torrance	9/21/2017	Intuitive-00301811	Intuitive-00301830
DX1767.222	Sales, License, and Service Agreement between Intuitive Surgical and Good Samaritan Regional Health Center, d/b/a SSM Health Good Samaritan Hospital - Mt. Vernon	9/25/2017	Intuitive-00167226	Intuitive-00167238
DX1767.223	Amendment to the Sales and License Agreement and to the Service Agreement between Intuitive Surgical and Mayo Clinic	9/28/2017	Intuitive-00343746	Intuitive-00343750
DX1767.224	Sales License and Service Agreement between Intuitive Surgical and The Johns Hopkins Hospital	9/29/2017	Intuitive-00614922	Intuitive-00614922.0019
DX1767.225	Loan Agreement between Banner University Medical Center Phoenix and Intuitive Surgical	10/5/2017	Intuitive-00006283	Intuitive-00006285
DX1767.226	Sales, License and Service Agreement between Intuitive Surgical and Kaiser Foundation Hospitals - Moanalua Medical Center	10/20/2017	Intuitive-01758798	Intuitive-01758818
DX1767.227	Sales, License, and Service Agreement between Intuitive Surgical and University of Southern California on behalf of its Keck Hospital of USC	10/23/2017	Intuitive-00302196	Intuitive-00302208
DX1767.228	Loan Agreement between Intuitive Surgical and Keck School of Medicine of USC	11/3/2017	Intuitive-01801217	Intuitive-01801219
DX1767.229	Amendment to the Sales and License Agreement and to the Service Agreement between Intuitive Surgical and Mayo Clinic	11/10/2017	Intuitive-00344477	Intuitive-00344482
DX1767.230	Amendment to the Sales and License Agreement & to the Service Agreement between Intuitive Surgical and Mayo Clinic	11/17/2017	Intuitive-00344392	Intuitive-00344396
DX1767.231	Sales, License, and Service Agreement between Intuitive Surgical and Exeter Hospital	11/22/2017	Intuitive-00302518	Intuitive-00302529
DX1767.232	Sales, License and Service Agreement between Intuitive Surgical and Kaiser Foundation Hospitals - Panorama City Medical Center	11/30/2017	Intuitive-01763529	Intuitive-01763549
DX1767.233	Sales, License, and Service Agreement between Intuitive Surgical and Beth Israel Deaconess Hospital-Milton	12/11/2017	Intuitive-00061804	Intuitive-00061814
DX1767.234	Amendment to the Sales, License, and Service Agreement between Intuitive Surgical and Advocate Health and Hospitals Corporation on behalf of BroMenn Medical Center	12/20/2017	Intuitive-01764701	Intuitive-01764705
DX1767.235	Use, License and Service Agreement between Intuitive Surgical and The Johns Hopkins Health System Corporation	12/28/2017	Intuitive-00227564	Intuitive-00227622
DX1767.236	Loan Agreement between Intuitive Surgical and Keck School of Medicine of USC	1/23/2018	Intuitive-01767352	Intuitive-01767354
DX1767.237	Equipment Loan and Pilot Agreement between Intuitive Surgical and Advocate Health and Hospitals Corporation	2/7/2018	Intuitive-00064174	Intuitive-00064187
DX1767.238	Sales, License, and Service Agreement between Intuitive Surgical and SSM Health Care of Oklahoma, Inc., an Oklahoma nonprofit corporation, owning and operating St. Anthony Hospital	2/8/2018	Intuitive-00303601	Intuitive-00303613
DX1767.239	Lease and Transaction Agreement between Intuitive Surgical and Seton Northwest Hospital	02/09/2018	Intuitive-00449341	Intuitive-00449350
DX1767.240	Sales, License, and Service Agreement between Intuitive Surgical and SSM Health Care of Wisconsin, Inc. on behalf of St. Mary's Hospital	2/20/2018	Intuitive-00303895	Intuitive-00303906
DX1767.241	Amendment 1 to The Lease Agreement between Intuitive Surgical and Franciscan Alliance, Inc	3/15/2018	Intuitive-00601480	Intuitive-00601481
DX1767.242	Use, License & Service Agreement between Intuitive Surgical and Northside Hospital Inc.	3/29/2018	Intuitive-01774459	Intuitive-01774479
DX1767.243	Use, License and Service Agreement between Intuitive Surgical and Northside Hospital-Cherokee	3/29/2018	Intuitive-00304138	Intuitive-00304158
DX1767.244	Amendment to the Sales, License and Service Agreement between Intuitive Surgical and Scottsdale Healthcare Hospitals doing business as HonorHealth on behalf of HonorHealth Scottsdale Shea Medical Center and HonorHealth Deer Valley Medical Center	4/23/2018	Intuitive-01776135	Intuitive-01776140
DX1767.245	Loan Agreement between Intuitive Surgical and University of Southern California	5/17/2018	Intuitive-01757103	Intuitive-01757104
DX1767.246	Use, License & Service Agreement between Intuitive Surgical and Northside Hospital-Forsyth	6/14/2018	Intuitive-01780950	Intuitive-01780971

DX1767.247	Use, License and Service Agreement between Intuitive Surgical and Northside Hospital-Forsyth	6/14/2018	Intuitive-00305265	Intuitive-00305286
DX1767.248	Sales, License, and Service Agreement between Intuitive Surgical and Regents of the University of Michigan	6/20/2018	Intuitive-00063874	Intuitive-00063884
DX1767.249	Sales, License, and Service Agreement between Intuitive Surgical and Winchester Hospital	06/25/2018	Intuitive-00063892	Intuitive-00063903
DX1767.250	Use, License & Service Agreement between Intuitive Surgical and Pomona Valley Hospital Medical Center	7/6/2018	Intuitive-00305910	Intuitive-00305929
DX1767.251	Amendment to the Sales, License and Service Agreement between Intuitive Surgical and Memorial Health Services dba Memorial Care on behalf of Memorial Care Long Beach Medical Center	7/20/2018	Intuitive-01785187	Intuitive-01785194
DX1767.252	Use, License and Service Agreement between Intuitive Surgical and Mayo Foundation for Medical Education and Research	8/31/2018	Intuitive-00098723	Intuitive-00098742
DX1767.253	Amendment to the Sales, License and Service Agreement between Intuitive Surgical and Memorial Health Services dba Memorial Care on behalf of Orange Coast Memorial Medical Center	8/31/2018	Intuitive-00307312	Intuitive-00307317
DX1767.254	Amendment to the Sales, License and Service Agreement between Intuitive Surgical and Memorial Health Services dba Memorial Care on behalf of Saddleback Memorial Medical Center	8/31/2018	Intuitive-01791589	Intuitive-01791595
DX1767.255	Sales, License, and Service Agreement between Intuitive Surgical and Valley Medical Center	8/31/2018	Intuitive-00306656	Intuitive-00306671
DX1767.256	Banner Health Nineteenth Amendment to terms and Conditions of Purchase of Robotic Surgical Equipment Agreement	8/31/2018	Intuitive-01788399	Intuitive-01788403
DX1767.257	Banner Health Twentieth Amendment to Terms and Conditions of Purchase of Robotic Surgical Equipment Agreement	9/5/2018	Intuitive-01789163	Intuitive-01789167
DX1767.258	Use, License, and Service Agreement between Intuitive Surgical and Banner University Medical Center Phoenix	09/21/2018	Intuitive-00307425	Intuitive-00307444
DX1767.259	Amendment to the Use, License, and Service Agreement and Lease Agreement between Banner University Medical Center Phoenix	09/21/2018	Intuitive-01848686	Intuitive-01848689
DX1767.260	Sales, License, and Service Agreement between Intuitive Surgical and Ardent Health Services on behalf of UT Health Tyler	09/25/2018	Intuitive-00065047	Intuitive-00065059
DX1767.261	Sales, License, and Service Agreement between Intuitive Surgical and Beth Israel Deaconess Medical Center	09/25/2018	Intuitive-00308581	Intuitive-00308593
DX1767.262	Use, License & Service Agreement between Intuitive Surgical and The Board of Trustees of the University of Illinois on behalf of the University of Illinois Hospital and Health Sciences System	9/28/2018	Intuitive-00099466	Intuitive-00099485
DX1767.263	Amendment 4 to the Sales, License and Service Agreement between Intuitive Surgical and Northwestern Memorial Healthcare	11/29/2018	Intuitive-00324111	Intuitive-00324120
DX1767.264	Amendment 4 to the Sales, License and Service Agreement between Intuitive Surgical and Northwestern Memorial Healthcare	11/29/2018	Intuitive-01802724	Intuitive-01802733
DX1767.265	Sales, License, and Service Agreement between Intuitive Surgical and The Children's Hospital Corporation dba Boston Children's Hospital	12/05/2018	Intuitive-00066202	Intuitive-00066214
DX1767.266	Amendment to the Sales, License, and Service Agreement between Intuitive Surgical and The Children's Hospital Corporation dba Boston Children's Hospital	12/05/2018	Intuitive-02010557	Intuitive-02010560
DX1767.267	Transaction Agreement between Intuitive Surgical and Advocate Aurora Health Inc. dba Advocate Lutheran General Hospital	12/14/2018	Intuitive-01809774	Intuitive-01809779
DX1767.268	Transaction Agreement between Intuitive Surgical and Advocate Aurora Health Inc. dba Condell Medical Center	12/14/2018	Intuitive-01809859	Intuitive-01809864
DX1767.269	Use, License and Service Agreement between Intuitive Surgical and Lahey Clinic Hospital	12/19/2018	Intuitive-00066639	Intuitive-00066650
DX1767.270	Lease Agreement between Intuitive Surgical and Lahey Clinic Hospital	12/19/2018	Intuitive-01814033	Intuitive-01814049
DX1767.271	Amendment to the Lease Agreement between Intuitive Surgical and Banner University Medical Center Phoenix	12/27/2018	Intuitive-01027017	Intuitive-01027021
DX1767.272	Amendment to the Transaction Agreement between Intuitive Surgical and Advocate Aurora Health Inc. dba Advocate Lutheran General Hospital	01/18/2019	Intuitive-01814258	Intuitive-01814258
DX1767.273	Lease and Transaction Agreement between Intuitive Surgical and Seton Family of Hospitals on behalf of Seton Medical Center Highland Lakes	02/01/2019	Intuitive-01815307	Intuitive-01815315
DX1767.274	Amendment to the Loan Agreement between Intuitive Surgical and Keck School of Medicine of USC	2/6/2019	Intuitive-01826956	Intuitive-01826956
DX1767.275	Sales, License, and Service Agreement between Intuitive Surgical and Lovelace Women's Hospital	03/05/2019	Intuitive-00563372	Intuitive-00563386
DX1767.276	Use, License, and Service Agreement between Intuitive Surgical and Duke University Health System Inc.	03/07/2019	Intuitive-00313235	Intuitive-00313262
DX1767.277	Lease Agreement between Intuitive Surgical and Franciscan Alliance, Inc	3/7/2019	Intuitive-00059668	Intuitive-00059685
DX1767.278	Banner Desert Medical Center Twenty-second amendment to the Terms and conditions of purchase of robotic surgical equipment agreement	3/22/2019	Intuitive-01819854	Intuitive-01819858
DX1767.279	Sales, License, and Service Agreement between Intuitive Surgical and Northside Hospital Inc.	3/29/2019	Intuitive-01822081	Intuitive-01822099
DX1767.280	Lease and Transaction Agreement between Intuitive Surgical and Ascension Seton	05/08/2019	Intuitive-00321730	Intuitive-00321739
DX1767.281	Amendment No. 2 to the Sales, License and Service Agreement between Intuitive Surgical and Scottsdale Healthcare Hospitals d/b/a HonorHealth on behalf of HonorHealth Scottsdale Thompson Peak Medical Center	5/16/2019	Intuitive-00321850	Intuitive-00321854

DX1767.282	Lease and Transaction Agreement between Intuitive Surgical and Ascension Seton	05/24/2019	Intuitive-01827075	Intuitive-01827084
DX1767.283	Lease and Transaction Agreement between Intuitive Surgical and Ascension Seton	06/07/2019	Intuitive-00321961	Intuitive-00321970
DX1767.284	Master Sales, License, and Service Agreement between Intuitive Surgical and Piedmont Healthcare, Inc.	6/10/2019	Intuitive-01828755	Intuitive-01828779
DX1767.285	Amendment to the Lease Agreement between Intuitive Surgical and Pomona Valley Hospital Medical Center	6/10/2019	Intuitive-01830579	Intuitive-01830580
DX1767.286	Franciscan Health Lafayette Amendment to the SLA	6/12/2019	Intuitive-01250362	Intuitive-01250364
DX1767.287	Sales, License, and Service Agreement between Intuitive Surgical and Winchester Medical Center	06/20/2019	Intuitive-00315215	Intuitive-00315230
DX1767.288	Master Lease Agreement between Intuitive Surgical and Kaiser Foundation Hospitals	7/15/2019	Intuitive-01837384	Intuitive-01837420
DX1767.289	Amendment to the Sales, License and Service Agreement between Intuitive Surgical and Northeast Georgia Medical Center	7/22/2019	Intuitive-00016624	Intuitive-00016629
DX1767.290	Sales, License, and Service Agreement between Intuitive Surgical and Winchester Medical Center	07/30/2019	Intuitive-00323384	Intuitive-00323401
DX1767.291	Amendment to the Sales, License and Service Agreement between Intuitive Surgical and Franciscan Alliance Inc., d/b/a Franciscan Health Lafayette East	8/5/2019	Intuitive-01250366	Intuitive-01250368
DX1767.292	Sales, License, and Service Agreement between Intuitive Surgical and Conway Regional Medical Center, Inc. d/b/a Conway Regional Health System	8/15/2019	Intuitive-00067540	Intuitive-00067547
DX1767.293	Lease Agreement between Intuitive Surgical and AMISUB of South Carolina, Inc. dba Piedmont Medical Center	8/30/2019	Intuitive-00939596	Intuitive-00939603
DX1767.294	Amendment to the Sales, License and Service Agreement between Intuitive Surgical and Valley Medical Center	9/4/2019	Intuitive-00313873	Intuitive-00313878
DX1767.295	Franciscan Alliance Second Amendment to the SLA	9/12/2019	Intuitive-01120451	Intuitive-01120452
DX1767.296	Sales, License, and Service Agreement between Intuitive Surgical and Conway Hospital	9/17/2019	Intuitive-00067924	Intuitive-00067935
DX1767.297	MDA Agreement 5060012030 Lease Agreement between Intuitive Surgical and University of Texas MD Anderson Cancer Center	09/24/2019	Intuitive-00068430	Intuitive-00068461
DX1767.298	Amendment 5 to the Sales, License and Service Agreement between Intuitive Surgical and Northwestern Memorial Healthcare on behalf of Northwestern Memorial Hospital	9/24/2019	Intuitive-01845987	Intuitive-01845992
DX1767.299	Sales, License, and Service Agreement between Intuitive Surgical and Franciscan Alliance	9/25/2019	Intuitive-00314658	Intuitive-00314672
DX1767.300	Use, License and Service Agreement between Intuitive Surgical and Legacy Health	9/26/2019	Intuitive-01846832	Intuitive-01846849
DX1767.301	True Lease Schedule No. 3 to Master Lease Agreement between Intuitive Surgical and Kaiser Foundation Hospitals	9/30/2019	Intuitive-00316818	Intuitive-00316823
DX1767.302	Amendment No. 3 to the Sales, License and Service Agreement between Intuitive Surgical and Scottsdale Healthcare Hospitals d/b/a HonorHealth on behalf of HonorHealth Scottsdale Shea Medical Center	11/8/2019	Intuitive-00316801	Intuitive-00316805
DX1767.303	Master Sales, License, and Service Agreement between Intuitive Surgical and Northside Hospital	11/13/2019	Intuitive-00160663	Intuitive-00160690
DX1767.304	Amendment to the Lease Agreement between Intuitive Surgical and AMISUB of South Carolina, Inc.	11/26/2019	Intuitive-02012183	Intuitive-02012185
DX1767.305	Use, License and Service Agreement between Intuitive Surgical and Scottsdale Healthcare Hospitals d/b/a Honor Health John C. Lincoln Medical Center	12/2/2019	Intuitive-00316743	Intuitive-00316761
DX1767.306	Use, License and Service Agreement between Intuitive Surgical and Advocate Aurora Health dba Advocate Christ Medical Center	12/09/2019	Intuitive-00094417	Intuitive-00094428
DX1767.307	Lease Agreement between Intuitive Surgical and Advocate Aurora Health dba Advocate Christ Medical Center	12/09/2019	Intuitive-00094429	Intuitive-00094434
DX1767.308	Use, License and Service Agreement between Intuitive Surgical and Kaiser Permanente San Jose Medical Center	12/10/2019	Intuitive-01857701	Intuitive-01857708
DX1767.309	Use, License and Service Agreement between Intuitive Surgical and Kaiser Permanente Santa Clara Medical Center	12/10/2019	Intuitive-01858610	Intuitive-01858617
DX1767.310	Use, License and Service Agreement between Intuitive Surgical and Kaiser Permanente Modesto Medical Center	12/10/2019	Intuitive-01859110	Intuitive-01859117
DX1767.311	Sales, License, and Service Agreement between Intuitive Surgical and Northwestern Memorial Healthcare	12/16/2019	Intuitive-01862315	Intuitive-01862329
DX1767.312	Sales, License, and Service Agreement between Intuitive Surgical and Northeast Georgia Medical Center	12/20/2019	Intuitive-01863179	Intuitive-01863190
DX1767.313	Transaction Agreement between Intuitive Surgical and Advocate Aurora Health Inc. dba Advocate Christ Medical Center	12/24/2019	Intuitive-01867911	Intuitive-01867916
DX1767.314	Banner Health Twenty-third amendment to the Terms and conditions of purchase of robotic surgical equipment agreement	12/26/2019	Intuitive-00936158	Intuitive-00936166
DX1767.315	Sales, License, and Service Agreement between Intuitive Surgical and Indiana University Health d/b/a IU Health Ball Memorial Hospital	12/27/2019	Intuitive-00935569	Intuitive-00935582
DX1767.316	Sales, License, and Service Agreement between Intuitive Surgical and Indiana University Health dba IU Health Arnett Hospital	12/27/2019	Intuitive-01030081	Intuitive-01030094
DX1767.317	Loan Agreement between Intuitive Surgical and University of Southern California on behalf of Keck School of Medicine USC	12/31/2019	Intuitive-01849868	Intuitive-01849869
DX1767.318	Service Renewal Addendum between Intuitive Surgical and Hillcrest Hospital South - OK	01/15/2020	Intuitive-00060709	Intuitive-00060710
DX1767.319	Sales, License, and Service Agreement between Intuitive Surgical and Mayo Clinic Hospital-Saint Mary's Campus	1/24/2020	Intuitive-01882252	Intuitive-01882262

DX1767.320	Sales, License, and Service Agreement between Intuitive Surgical and Mayo Clinic-Jacksonville	1/24/2020	Intuitive-01882263	Intuitive-01882273
DX1767.321	Amendment to the Master Sales, License, and Service Agreement between Intuitive Surgical and Piedmont Healthcare, Inc.	2/18/2020	Intuitive-01883098	Intuitive-01883107
DX1767.322	Master Sales, License, and Service Agreement between Intuitive Surgical and Providence Health & Services	4/6/2020	Intuitive-01886224	Intuitive-01886246
DX1767.323	Use, License and Service Agreement between Intuitive Surgical and Marin General Hospital	4/30/2020	Intuitive-01889952	Intuitive-01889962
DX1767.324	Lease Agreement between Intuitive Surgical and Marin General Hospital	4/30/2020	Intuitive-01889963	Intuitive-01889968
DX1767.325	Service Agreement between Intuitive Surgical and Ardent Health Services	06/04/2020	Intuitive-00563783	Intuitive-00563787
DX1767.326	Service Renewal Addendum between Intuitive Surgical and AHS Management Company	06/18/2020	Intuitive-00564032	Intuitive-00564037
DX1767.327	Use, License & Service Agreement between Intuitive Surgical and The Board of Trustees of the University of Illinois on behalf of the University of Illinois Hospital and Health Sciences System	6/22/2020	Intuitive-01895728	Intuitive-01895746
DX1767.328	Amendment No.1 to Amendment No.3 to Sales, License, and Service Agreement between Intuitive Surgical and Honor Health fka Scottsdale Healthcare Hospitals on behalf of HonorHealth Scottsdale Shen Medical Center	6/29/2020	Intuitive-00936941	Intuitive-00936942
DX1767.329	Amendment to the Use, License and Service Agreement between Intuitive Surgical and The Johns Hopkins Health System Corporation	7/1/2020	Intuitive-01897944	Intuitive-01897949
DX1767.330	Use, License, and Service Agreement between Intuitive Surgical and Lovelace Women's Hospital	07/21/2020	Intuitive-00564485	Intuitive-00564498
DX1767.331	Lease Agreement between Intuitive Surgical and Lovelace Women's Hospital	07/21/2020	Intuitive-00564499	Intuitive-00564504
DX1767.332	Lease Agreement between Intuitive Surgical and Kaiser-San Leandro Medical Center	7/23/2020	Intuitive-01898984	Intuitive-01898990
DX1767.333	Lease Agreement between Intuitive Surgical and Kaiser-Hospital and Rehabilitation Center	7/23/2020	Intuitive-01899164	Intuitive-01899170
DX1767.334	Sales, License, and Service Agreement between Intuitive Surgical and Lovelace Women's Health System	08/05/2020	Intuitive-01260436	Intuitive-01260450
DX1767.335	Use, License & Service Agreement between Intuitive Surgical and Northwestern Memorial Healthcare	8/21/2020	Intuitive-01900884	Intuitive-01900902
DX1767.336	Amendment to the Loan Agreement between Intuitive Surgical and Keck School of Medicine of USC	9/11/2020	Intuitive-01903708	Intuitive-01903708
DX1767.337	Amendment 2 to the Loan Agreement between Intuitive Surgical and Keck School of Medicine of USC	9/11/2020	Intuitive-01903709	Intuitive-01903709
DX1767.338	Master Sales, License, and Service Agreement between Intuitive Surgical and Franciscan Alliance, Inc	9/28/2020	Intuitive-01255224	Intuitive-01255248
DX1767.339	Transaction Agreement between Intuitive Surgical and Franciscan Alliance, Inc., d/b/a Franciscan Health Crawfordsville	9/28/2020	Intuitive-01121443	Intuitive-01121447
DX1767.340	Use, License, and Service Agreement between Intuitive Surgical and Banner Health	10/20/2020	Intuitive-01911721	Intuitive-01911737
DX1767.341	Transaction Agreement between Intuitive Surgical and Banner Ocotillo Medical Center	10/20/2020	Intuitive-01911738	Intuitive-01911740
DX1767.342	Transaction Agreement between Banner University Medical Center Tucson	11/9/2020	Intuitive-01912685	Intuitive-01912689
DX1767.343	Transaction Agreement between Intuitive Surgical and Banner University Medical Center South	11/9/2020	Intuitive-01916270	Intuitive-01916272
DX1767.344	Transaction Agreement between Intuitive Surgical and Banner University Medical Center Phoenix	11/9/2020	Intuitive-01916281	Intuitive-01916284
DX1767.345	Transaction Agreement between Intuitive Surgical and Banner Thunderbird Medical Center	11/9/2020	Intuitive-01916285	Intuitive-01916289
DX1767.346	Transaction Agreement between Intuitive Surgical and Banner North Colorado Medical Center	11/9/2020	Intuitive-01916300	Intuitive-01916303
DX1767.347	Transaction Agreement between Intuitive Surgical and Banner McKee Medical Center	11/9/2020	Intuitive-01916304	Intuitive-01916307
DX1767.348	Transaction Agreement between Intuitive Surgical and Banner Ironwood Medical Center	11/9/2020	Intuitive-01916308	Intuitive-01916311
DX1767.349	Transaction Agreement between Intuitive Surgical and Banner Goldfield Medical Center	11/9/2020	Intuitive-01916312	Intuitive-01916315
DX1767.350	Transaction Agreement between Intuitive Surgical and Banner Estrella Medical Center	11/9/2020	Intuitive-01916316	Intuitive-01916319
DX1767.351	Transaction Agreement between Intuitive Surgical and Banner Desert Medical Center	11/9/2020	Intuitive-01916320	Intuitive-01916324
DX1767.352	Transaction Agreement between Intuitive Surgical and Banner Casa Grande Medical Center	11/9/2020	Intuitive-01916330	Intuitive-01916332
DX1767.353	Transaction Agreement between Intuitive Surgical and Banner Baywood Medical Center	11/9/2020	Intuitive-01916333	Intuitive-01916336
DX1767.354	Transaction Agreement between Intuitive Surgical and Banner Gateway Medical Center	11/9/2020	Intuitive-01916341	Intuitive-01916344
DX1767.355	Lease Agreement between Intuitive Surgical and King County Public Hospital District No. 2 d/b/a Evergreen Health	12/10/2020	Intuitive-01921735	Intuitive-01921742
DX1767.356	Use, License, and Service Agreement between King County Public Hospital District	12/10/2020	Intuitive-01921743	Intuitive-01921757
DX1767.357	Use, License & Service Agreement between Intuitive Surgical and The Board of Trustees of the University of Illinois on behalf of the University of Illinois Hospital and Health Sciences System	12/11/2020	Intuitive-01919284	Intuitive-01919302
DX1767.358	Transaction Agreement between Intuitive Surgical and Advocate Aurora Health Inc. dba Advocate Christ Medical Center	12/23/2020	Intuitive-01924369	Intuitive-01924372

DX1767.359	Transaction Agreement between Intuitive Surgical and Advocate Aurora Health Inc. dba Advocate Good Samaritan Hospital	12/23/2020	Intuitive-01924373	Intuitive-01924376
DX1767.360	Transaction Agreement between Intuitive Surgical and Advocate Aurora Health Inc. dba Aurora St. Luke's Medical Center	12/23/2020	Intuitive-01924377	Intuitive-01924380
DX1767.361	Transaction Agreement between Intuitive Surgical and Advocate Aurora Health Inc. dba Advocate Illinois Masonic Medical Center	12/23/2020	Intuitive-01924381	Intuitive-01924384
DX1767.362	Transaction Agreement between Intuitive Surgical and Advocate Aurora Health Inc. dba Advocate Lutheran General Hospital	12/23/2020	Intuitive-01924385	Intuitive-01924388
DX1767.363	Transaction Agreement between Intuitive Surgical and Advocate Aurora Health Inc. dba Advocate South Suburban Hospital	12/23/2020	Intuitive-01924389	Intuitive-01924394
DX1767.364	Amendment No. 1 to the Use, License and Service Agreement & Lease Agreement between Intuitive Surgical and USC Verdugo Hills Hospital	12/28/2020	Intuitive-01927498	Intuitive-01927499
DX1767.365	Use, License and Service Agreement between Intuitive Surgical and HonorHealth dba HonorHealth Scottsdale Shen Medical Center	12/31/2020	Intuitive-01926982	Intuitive-01926999
DX1767.366	Sales, License, and Service Agreement between Intuitive Surgical and Conway Hospital	12/31/2020	Intuitive-01927099	Intuitive-01927109
DX1767.367	Kaiser Foundation hospitals True Lease Schedule to Master Lease Agreement Contract Reference Number 441034	12/31/2020	Intuitive-01926834	Intuitive-01926840
DX1767.368	Loan Agreement between Intuitive Surgical and Banner University Medical Center Phoenix	1/19/2021	Intuitive-01929027	Intuitive-01929029
DX1767.369	Loan Agreement between Intuitive Surgical and Banner Thunderbird Medical Center	1/19/2021	Intuitive-01929030	Intuitive-01929032
DX1767.370	Loan Agreement between Intuitive Surgical and Banner McKee Medical Center	1/19/2021	Intuitive-01929033	Intuitive-01929035
DX1767.371	Loan Agreement between Intuitive Surgical and Banner Gateway Medical Center	1/19/2021	Intuitive-01929036	Intuitive-01929038
DX1767.372	Loan Agreement between Intuitive Surgical and Banner Estrella Medical Center	1/19/2021	Intuitive-01929039	Intuitive-01929041
DX1767.373	Loan Agreement between Intuitive Surgical and Banner Desert Medical Center	1/19/2021	Intuitive-01929042	Intuitive-01929044
DX1767.374	Loan Agreement between Intuitive Surgical and Banner Del Webb Medical Center	1/19/2021	Intuitive-01929045	Intuitive-01929047
DX1767.375	Loan Agreement between Intuitive Surgical and Banner University Medical Center Tucson	1/19/2021	Intuitive-01929048	Intuitive-01929050
DX1767.376	Consolidated Services Agreement between Intuitive Surgical and Banner Health	1/19/2021	Intuitive-01929318	Intuitive-01929320
DX1767.377	Amendment to the Sales, License and Service Agreement between Intuitive Surgical and University of Southern California on behalf of Keck Hospital of USC	2/15/2021	Intuitive-01931949	Intuitive-01931956
DX1767.378	Amendment to the Sales, License and Service Agreement between Intuitive Surgical and University of Southern California on behalf of Keck Hospital of USC	2/15/2021	Intuitive-01931957	Intuitive-01931961
DX1767.379	Amendment to the Sales, License and Service Agreement between Intuitive Surgical and SSM Health Care of Oklahoma, Inc., an Oklahoma nonprofit corporation, owning and operating St. Anthony Hospital	2/19/2021	Intuitive-01932359	Intuitive-01932363
DX1767.380	Sales, License, and Service Agreement between Intuitive Surgical and AHS Hillcrest Medical Center	03/10/2021	Intuitive-00795203	Intuitive-00795217
DX1767.381	Sales, License, and Service Agreement between Intuitive Surgical and AHS Hillcrest Medical Center	03/10/2021	Intuitive-01934389	Intuitive-01934403
DX1767.382	Lease and Transaction Agreement between Intuitive Surgical and Ascension Seton Highland Lakes	03/20/2021	Intuitive-01937214	Intuitive-01937221
DX1767.383	Amendment to the Lease Agreement between Intuitive Surgical and USC Verdugo Hills Hospital	3/20/2021	Intuitive-01934959	Intuitive-01934959
DX1767.384	Loan Agreement between Intuitive Surgical and Banner Casa Grande Medical Center	3/23/2021	Intuitive-01936873	Intuitive-01936874
DX1767.385	Loan Agreement between Intuitive Surgical and Banner Boswell Medical Center	3/23/2021	Intuitive-01936875	Intuitive-01936876
DX1767.386	Loan Agreement between Intuitive Surgical and Banner Estrella Medical Center	3/23/2021	Intuitive-01936877	Intuitive-01936878
DX1767.387	Loan Agreement between Intuitive Surgical and Banner Gateway Medical Center	3/23/2021	Intuitive-01936879	Intuitive-01936880
DX1767.388	Master Sales, License, and Service Agreement between Intuitive Surgical and Indiana University Health	3/30/2021	Intuitive-01940975	Intuitive-01941005
DX1767.389	Sales, License, and Service Agreement between Intuitive Surgical and AHS Hillcrest Medical Center	04/15/2021	Intuitive-02011886	Intuitive-02011900
DX1767.390	Sales, Lease, and Service Agreement between Intuitive Surgical and Beth Israel Deaconess Medical Center Inc.	05/14/2021	Intuitive-01946359	Intuitive-01946370
DX1767.391	Amendment to the Transaction Agreement between Intuitive Surgical and Banner Thunderbird Medical Center	5/19/2021	Intuitive-01946693	Intuitive-01946694
DX1767.392	Transaction Agreement between Intuitive Surgical and Banner McKee Medical Center	5/19/2021	Intuitive-01946695	Intuitive-01946697
DX1767.393	Lease Agreement between Intuitive Surgical and Regents of the University of Michigan	6/11/2021	Intuitive-01950164	Intuitive-01950181
DX1767.394	Sales, License, and Service Agreement between Intuitive Surgical and Regents of the University of Michigan	6/11/2021	Intuitive-01950182	Intuitive-01950192
DX1767.395	Lease Transaction Agreement between Intuitive Surgical and Aurora Health Care Southern Lakes Inc. dba Aurora Medical Center - Kenosha	06/15/2021	Intuitive-01950863	Intuitive-01950871
DX1767.396	Lease Agreement between Intuitive Surgical and University of Southern California on behalf of Keck Hospital of USC	6/15/2021	Intuitive-01950496	Intuitive-01950501

DX1767.397	Use, License & Service Agreement between Intuitive Surgical and University of Southern California on behalf of Keck Hospital of USC	6/15/2021	Intuitive-01950502	Intuitive-01950514
DX1767.398	Amendment to the Master Sales, License and Service Agreement between Providence Health & Services	6/18/2021	Intuitive-01950836	Intuitive-01950839
DX1767.399	Kaiser Foundation hospitals True Lease Schedule to Master Lease Agreement Contract Reference Number 405806	6/18/2021	Intuitive-01951989	Intuitive-01951995
DX1767.400	Use, License, and Service Agreement between Intuitive Surgical and Winchester Medical Center	06/23/2021	Intuitive-01952308	Intuitive-01952324
DX1767.401	Lease Agreement between Intuitive Surgical and Providence Health & Services on behalf of Providence Health St. John's Hospital & Health Center	6/25/2021	Intuitive-01952786	Intuitive-01952791
DX1767.402	Amendment to the Lease Agreement between Intuitive Surgical and Marin General Hospital	6/29/2021	Intuitive-01953854	Intuitive-01953854
DX1767.403	Amendment 3 to the Loan Agreement between Intuitive Surgical and Keck School of Medicine of USC	7/15/2021	Intuitive-01957604	Intuitive-01957604
DX1767.404	Lease Agreement between Intuitive Surgical and HonorHealth dba John C. Lincoln Medical Center	7/26/2021	Intuitive-01959894	Intuitive-01959911
DX1767.405	Loan Agreement between Intuitive Surgical and Banner Gateway Medical Center	8/18/2021	Intuitive-01963679	Intuitive-01963683
DX1767.406	Amendment to the Master Sales, License and Service Agreement between Intuitive Surgical and Northside Hospital, Inc	8/26/2021	Intuitive-01962868	Intuitive-01962871
DX1767.407	Use, License and Service Agreement between Intuitive Surgical and Conway Regional Medical Center	8/31/2021	Intuitive-01962773	Intuitive-01962791
DX1767.408	Amendment to the Lease Agreement between Intuitive and Lahey Clinic Hospital Inc.	09/15/2021	Intuitive-01966439	Intuitive-01966439
DX1767.409	Sales, License, and Service Agreement between Intuitive Surgical and Northwestern Memorial Healthcare on behalf of Central DuPage Hospital	9/15/2021	Intuitive-01964622	Intuitive-01964638
DX1767.410	Sales, License, and Service Agreement between Intuitive Surgical and Northwestern Memorial Healthcare on behalf of Delnor-Community Hospital	9/15/2021	Intuitive-01964639	Intuitive-01964655
DX1767.411	Amendment to the Use, License and Service Agreement & Lease Agreement between Intuitive Surgical and Providence Health & Services-Washington, dba Providence Sacred Heart Medical Center	9/17/2021	Intuitive-01967697	Intuitive-01967698
DX1767.412	Transaction Agreement between Intuitive Surgical and Advocate Aurora Health Inc. dba Advocate Christ Medical Center	09/29/2021	Intuitive-01970128	Intuitive-01970131
DX1767.413	Lease Transaction Agreement between Intuitive Surgical and Aurora Health Care Southern Lakes Inc. dba Aurora St. Luke's Medical Center	10/01/2021	Intuitive-01974345	Intuitive-01974354
DX1767.414	First Amendment to Master Sales, License, and Service Agreement between Franciscan Alliance, Inc. and Intuitive Surgical	10/27/2021	Intuitive-01260395	Intuitive-01260399
DX1767.415	First Amendment to Master Sales, License, and Service Agreement between Franciscan Alliance, Inc. and Intuitive Surgical	10/29/2021	FRANCISCAN-00000423	FRANCISCAN-00000427
DX1767.416	Amendment to the Amendment to the Master Sales, License and Service Agreement between Intuitive Surgical and Providence Health & Services	10/31/2021	Intuitive-01973995	Intuitive-01973996
DX1767.417	Sales, License, and Service Agreement between Intuitive Surgical and Northwestern Memorial Healthcare on behalf of Northwestern Medicine McHenry Hospital	11/24/2021	Intuitive-01978623	Intuitive-01978639
DX1767.418	Amendment 4 to the Loan Agreement between Intuitive Surgical and Keck School of Medicine	12/2/2021	Intuitive-01990115	Intuitive-01990115
DX1767.419	Use, License, and Service Agreement between Intuitive Surgical and Lahey Clinic Hospital Inc.	12/10/2021	Intuitive-01981958	Intuitive-01981976
DX1767.420	Use, License, and Service Agreement between Intuitive Surgical and Beth Israel Lahey Health Inc.	12/16/2021	Intuitive-01984147	Intuitive-01984163
DX1767.421	Amendment to the Sales, License and Service Agreement between Intuitive Surgical and Good Samaritan Regional Health Center, a Missouri nonprofit corporation, d/b/a SSM Health Good Samaritan Hospital - Mt. Vernon	12/16/2021	Intuitive-01983447	Intuitive-01983448
DX1767.422	Use, License and Service Agreement between Intuitive Surgical and HonorHealth dba HonorHealth Deer Valley Medical Center	12/16/2021	Intuitive-01987353	Intuitive-01987370
DX1767.423	Lease Agreement between Intuitive Surgical and Providence Health & Services on behalf of Providence Alaska Medical Center	12/17/2021	Intuitive-01988288	Intuitive-01988294
DX1767.424	Sales, License, and Service Agreement between Intuitive Surgical and Lovelace Health System LLC dba Lovelace Medical Center	12/21/2021	Intuitive-01984735	Intuitive-01984749
DX1767.425	Crescent City Surgical Center Operating Company ULSA	12/28/2021	Intuitive-01987738	Intuitive-01987756
DX1767.426	Lease Agreement between Intuitive Surgical and Providence Health & Services on behalf of Covenant Medical Center-19th Street Camput	12/30/2021	Intuitive-01989055	Intuitive-01989060
DX1767.427	Amendment to the Use, License and Servie Agreement & Lease Agreement between Intuitive Surgical and University of Southern California on behalf of Keck Hospital of USC	12/30/2021	Intuitive-01990306	Intuitive-01990307
DX1767.428	Loan Agreement between Intuitive Surgical and Keck Hospital of USC	2/9/2022	Intuitive-01993179	Intuitive-01993183
DX1767.429	Sales, License, and Service Agreement between Intuitive Surgical and Northwestern Memorial Healthcare	2/17/2022	Intuitive-01993658	Intuitive-01993673
DX1767.430	Sales, License, and Service Agreement between Intuitive Surgical and Banner Boswell Medical Center	03/18/2022	Intuitive-02000683	Intuitive-02000694
DX1767.431	Sales, License, and Service Agreement between Intuitive Surgical and Northwestern Memorial Healthcare on behalf of Northwestern Medicine Grayslake Outpatient Center	3/24/2022	Intuitive-01999030	Intuitive-01999045

DX1767.432	Sales, License, and Service Agreement between Intuitive Surgical and Pullman Regional Hospital	3/31/2022	Intuitive-02000753	Intuitive-02000763
DX1767.433	Amendment to the Use, License, and Service Agreement and Lease Agreement between Banner Health	04/06/2022	Intuitive-02001281	Intuitive-02001281
DX1767.434	Transaction Agreement between Intuitive Surgical and Banner Fort Collins Medical Center	4/6/2022	Intuitive-02001278	Intuitive-02001280
DX1767.435	Sales and Service Agreement between Intuitive Surgical and Newark Beth Israel Medical Center	12/19/2022	Intuitive-01525750	Intuitive-01525766

Compilation of Intuitive Communications re Patient Safety.					
Def.'s Temporary Exhibit No.	Description	Date	Beg Bates	End Bates	Objections
DX1768.01	Letter from Intuitive to Eastbourne District General Hospital	02/27/17	Intuitive-01019584	Intuitive-01019585	
DX1768.02	Letter from Hogan Lovells, on behalf of Intuitive, to Rebotix-Panama	04/21/2017	REBOTIX140044	REBOTIX140053	
DX1768.03	Letter from Hogan Lovells, on behalf of Intuitive, to Rebotix-Panama	05/10/2017	REBOTIX140654	REBOTIX140662	
DX1768.04	Letter from Intuitive to Eastbourne District General Hospital	06/15/17	Intuitive-00367722	Intuitive-00367723	
DX1768.05	Letter from Intuitive to Northwest Medical Center (draft)	05/10/2018	Intuitive-01020024	Intuitive-01020025	
DX1768.06	Letter from Intuitive to Clinique Charcol	06/04/18	Intuitive-01020229	Intuitive-01020230	
DX1768.07	Letter from Intuitive to Panama City Surgical Center	07/26/2018	Intuitive-00040125	Intuitive-00040127	
DX1768.08	Letter from Intuitive to Northfield	08/28/2018	REBOTIX144751	REBOTIX144756	
DX1768.09	Letter from Intuitive to Surgical Direct	08/28/2018	Restore-00086086	Restore-00086092	
DX1768.10	Letter from Intuitive to Conway Regional Medical Center	10/25/18	Intuitive-00032916	Intuitive-00032917	
DX1768.11	Letter from Intuitive to NCH North Naples Hospital	10/30/2018	Intuitive-01020935	Intuitive-01020936	
DX1768.12	Letter from Intuitive to Restore Robotics LLC	11/15/2018	Intuitive-00478439	Intuitive-00478444	
DX1768.13	Email from J. Watson to L. Otradovec re Follow up to our discussion this morning for a meeting regarding service & instrumentation	02/08/19	Intuitive-00153466	Intuitive-00153469	
DX1768.14	Letter from Intuitive to Restore Robotics LLC	02/12/2019	Restore-00025577	Restore-00025584	
DX1768.15	Letter from Intuitive to Baylor Scott and White	02/22/19	Intuitive-01072592	Intuitive-01072594	
DX1768.16	Letter from Intuitive to Baylor Scott and White	03/19/19	Intuitive-01119149	Intuitive-01119152	
DX1768.17	Letter from Intuitive to Conway Regional Medical Center	04/02/19	Intuitive-00157064	Intuitive-00157065	
DX1768.18	Letter from Intuitive to Northfield	04/16/2019	Rebotix145274	Rebotix145279	
DX1768.19	Letter from Intuitive to Conway Regional Medical Center	05/06/19	Intuitive-00446769	Intuitive-00446771	
DX1768.20	Letter from Intuitive to Baptist Health Medical Center Little Rock	05/07/19	Intuitive-00032950	Intuitive-00032951	
DX1768.21	Letter from Intuitive to Pacific Coast Surgical Center	05/07/2019	Intuitive-00019774	Intuitive-00019775	
DX1768.22	Letter from Intuitive to Jackson-Madison County General Hospital	05/09/19	Intuitive-00157093	Intuitive-00157094	
DX1768.23	Email from R. Bair to J. Cooley fw Instrument Report: 6/18/19	06/19/2019	Intuitive-00361133	Intuitive-00361136	
DX1768.24	Email from M. Davis to J. Blodgett re Reprogrammed da Vinci Instruments - Conway Regional Health System	07/02/19	Intuitive-00157210	Intuitive-00157211	
DX1768.25	Letter from Intuitive to McLaren Health Management Group	07/17/2019	Intuitive-00478591	Intuitive-00478592	
DX1768.26	Letter from Intuitive to White County Medical Center	07/17/2019	Intuitive-00341389	Intuitive-00341390	
DX1768.27	Email from A. Inacay to R. Bair re da Vinci System and 3rd Party Resetting I&A Lives	07/29/2019	Intuitive-00009500	Intuitive-00009502	
DX1768.28	Letter from Intuitive to Genesis Medical Center-Davenport	08/15/19	Intuitive-00048788	Intuitive-00048788	
DX1768.29	Email from B. Partridge to E. Grinberg fw da Vinci / Legacy Health - reprogrammed instrumentation concern	09/03/2019	Intuitive-01031534	Intuitive-01031535	
DX1768.30	Letter from Intuitive to Pullman Regional Hospital	09/09/19	Intuitive-00569245	Intuitive-00569247	
DX1768.31	Letter from Intuitive to Crescent City Surgical Center	09/11/19	Intuitive-00044524	Intuitive-00044526	
DX1768.32	Letter from Intuitive to New Hanover Regional Medical Center	10/01/2019	Intuitive-00048815	Intuitive-00048817	
DX1768.33	Email from G. Papit to G. Fiegel re Intuitive Follow up	10/06/19	REBOTIX174421	REBOTIX174426	
DX1768.34	Letter from Intuitive to Panama City Surgical Center	10/10/2019	PANAMA0000064	PANAMA0000066	
DX1768.35	Letter from Intuitive to Evergreen Healthcare	10/15/19	Intuitive-00048911	Intuitive-00048913	
DX1768.36	Letter from Intuitive to San Martin Surgery Center LLC	10/28/2019	Intuitive-00048920	Intuitive-00048922	
DX1768.37	Email from A. Inacay to J. Menold re Evergreen	10/31/19	Intuitive-00049029	Intuitive-00049032	
DX1768.38	Letter from Intuitive to The Jackson Madison County General Hospital District	11/04/2019	Intuitive-00049014	Intuitive-00049016	
DX1768.39	Email from J. Menold to A. Inacay re Evergreen	11/07/19	Intuitive-01032682	Intuitive-01032684	
DX1768.40	Letter from Intuitive to Norman Regional Hospital Authority, d/b/a Normal Regional Health System	11/11/2019	Intuitive-00049026	Intuitive-00049028	
DX1768.41	Letter from Intuitive to Thomas Memorial Hospital	11/19/2019	Intuitive-00373856	Intuitive-00373858	
DX1768.42	Letter from Intuitive to Marin General Hospital	11/26/2019	Intuitive-00049154	Intuitive-00049156	
DX1768.43	Letter from Intuitive to North Oaks Medical Center explaining service authorization	12/19/2019	Intuitive-00165844	Intuitive-00165844	
DX1768.44	Letter from Intuitive to Ardent Health Services	01/17/20	Intuitive-00562856	Intuitive-00562858	
DX1768.45	Letter from Intuitive to Ardent Health Services	01/17/20	Intuitive-00562853	Intuitive-00562855	
DX1768.46	Letter from Intuitive to Elite Robotic Surgery Center	02/12/20	Intuitive-01035008	Intuitive-01035011	
DX1768.47	Letter from Intuitive to Banner Health	02/14/2020	Intuitive-00986535	Intuitive-00986537	
DX1768.48	Letter from Intuitive to Indiana University Health Bloomington Hospital	02/25/20	Intuitive-00569308	Intuitive-00569310	
DX1768.49	Letter from Intuitive to King's Daughter Medical Center	02/26/2020	Intuitive-00674309	Intuitive-00674311	
DX1768.50	Letter from Intuitive to St. Vincent's Hospital	05/04/2020	Intuitive-00980925	Intuitive-00980927	
DX1768.51	Letter from Intuitive to Lowell General Hospital	05/14/2020	Intuitive-00569180	Intuitive-00569182	
DX1768.52	Letter from Intuitive to Abrazo Arrowhead Campus	05/21/20	Intuitive-00986752	Intuitive-00986754	
DX1768.53	Letter from Intuitive to Ballard Health	5/22/2020	Intuitive-00569252	Intuitive-00569254	

Compilation of Data Files					
Def.'s Temporary Exhibit No.	Description	Date	BegBates	EndBates	Objections
DX1769.01	Annual dV Procedure Datasets for Economic Team 4.29.22	04/29/2022	Intuitive-00706097	Intuitive-00706097	
DX1769.02	Procedure IQVIA Datasets for Economic Team 4.29.22	04/29/2022	Intuitive-00706098	Intuitive-00706098	
DX1769.03	Intuitive Sales data	n/a	Intuitive-00595406	Intuitive-00595406	
DX1769.04	Intuitive Sales data	n/a	Intuitive-00595407	Intuitive-00595407	
DX1769.05	Intuitive Sales data	n/a	Intuitive-00595408	Intuitive-00595408	
DX1769.06	Intuitive Sales data	n/a	Intuitive-00595409	Intuitive-00595409	

Compilation of K990144 Intuitive PMA Application Files.					
Def.'s Temporary Exhibit No.	Description	Date	Beg Bates	End Bates	Objections
DX1770.01	Volume 1: K990144 Intuitive PMA Application	11/26/1999	Intuitive-00692611	Intuitive-00692642	
DX1770.02	Volume 2: K990144 Intuitive PMA Application	11/26/1999	Intuitive-00692643	Intuitive-00692821	
DX1770.03	Volume 3: K990144 Intuitive PMA Application	11/26/1999	Intuitive-00692822	Intuitive-00692911	
DX1770.04	Volume 4: K990144 Intuitive PMA Application	11/26/1999	Intuitive-00692912	Intuitive-00693153	
DX1770.05	Volume 5: K990144 Intuitive PMA Application	11/26/1999	Intuitive-00693154	Intuitive-00693534	
DX1770.06	Volume 6: K990144 Intuitive PMA Application	11/26/1999	Intuitive-00693535	Intuitive-00694042	

Compilation of Intuitive Traditional 510(k) Submission K24095					
Def.'s Temporary Exhibit No.	Description	Date	Beg Bates	End Bates	Objections
DX1771.01	K214095 - Table of Contents	12/27/2021	Intuitive-02053643	Intuitive-02053645	
DX1771.02	K214095 - Section 1: Traditional 510(k) Acceptance Checklist	12/27/2021	Intuitive-02053729	Intuitive-02053742	
DX1771.03	K214095 - Section 2: Medical Device User Fee Cover Sheet	12/27/2021	Intuitive-02051528	Intuitive-02051529	
DX1771.04	K214095 - Section 3: CDRH Cover Sheet	12/27/2021	Intuitive-02053670	Intuitive-02053677	
DX1771.05	K214095 - Section 4: Cover Letter	12/27/2021	Intuitive-02053785	Intuitive-02053788	
DX1771.06	K214095 - Section 5: Indications for Use Statement	12/27/2021	Intuitive-02051550	Intuitive-02051552	
DX1771.07	K214095 - Section 6: 510(k) Summary	12/27/2021	Intuitive-02054131	Intuitive-02054139	
DX1771.08	K214095 - Section 7: Truthful and Accuracy Statement	12/27/2021	Intuitive-02054114	Intuitive-02054115	
DX1771.09	K214095 - Section 8: Class III Summary and Certification	12/27/2021	Intuitive-02051563	Intuitive-02051563	
DX1771.10	K214095 - Section 9: Financial Certification or Disclosure Statement	12/27/2021	Intuitive-02051568	Intuitive-02051568	
DX1771.11	K214095 - Section 10: Voluntary Consensus Standards	12/27/2021	Intuitive-02051573	Intuitive-02051573	
DX1771.12	K214095 - Section 11: Executive Summary	12/27/2021	Intuitive-02051577	Intuitive-02051584	
DX1771.13	K214095 - Section 12: Device Description	12/27/2021	Intuitive-02051698	Intuitive-02051703	
DX1771.14	K214095 - Section 13: Substantial Equivalence	12/27/2021	Intuitive-02051609	Intuitive-02051617	
DX1771.15	K214095 - Section 14: Proposed Labeling	12/27/2021	Intuitive-02052342	Intuitive-02052347	
DX1771.16	K214095 - Section 15: Reprocessing	12/27/2021	Intuitive-02054100	Intuitive-02054102	
DX1771.17	K214095 - Section 16: Biocompatibility	12/27/2021	Intuitive-02051651	Intuitive-02051651	
DX1771.18	K214095 - Section 17: Software and Cybersecurity	12/27/2021	Intuitive-02051655	Intuitive-02051655	
DX1771.19	K214095 - Section 18: Electromagnetic Compatibility (EMC) and Electrical Safety	12/27/2021	Intuitive-02051723	Intuitive-02051723	
DX1771.20	K214095 - Section 19: Performance Testing - Bench	12/27/2021	Intuitive-02053816	Intuitive-02053830	
DX1771.21	K214095 - Section 20: Performance Testing - Animal	12/27/2021	Intuitive-02051659	Intuitive-02051659	
DX1771.22	K214095 - Section 21: Performance Testing Clinical	12/27/2021	Intuitive-02051663	Intuitive-02051663	
DX1771.23	K214095 - Section 22: Human Factors	12/27/2021	Intuitive-02052318	Intuitive-02052323	
DX1771.24	K214095 - Appendix A1: Reprocessing Appendices, IS4000/IS4200, US (552246-07)	12/27/2021	Intuitive-02046437	Intuitive-02046478	
DX1771.25	K214095 - Appendix A2: Reprocessing Instructions, Instruments, IS4000/IS4200, US (551490-09)	12/27/2021	Intuitive-02046653	Intuitive-02046772	
DX1771.26	K214095 - Appendix A3: Addendum, Reprocessing Instructions, Instruments, IS4000/IS4200, US (554324-01)	12/27/2021	Intuitive-02047253	Intuitive-02047300	
DX1771.27	K214095 - Appendix A4: da Vinci X/Xi Instruments and Accessories User Manual Addendum (PN 554349-01)	12/27/2021	Intuitive-02047493	Intuitive-02047496	
DX1771.28	K214095 - Appendix B: Justification, Cleaning Efficacy for 18 Clinical Uses (PN 1070933)	12/27/2021	Intuitive-02052366	Intuitive-02052374	
DX1771.29	K214095 - Appendix C1: Reliability Verification Protocol for Fenestrated Bipolar Forceps (PN 862223-03P)	12/27/2021	Intuitive-02048083	Intuitive-02048115	
DX1771.30	K214095 - Appendix C2: Reliability Verification Report for Fenestrated Bipolar Forceps (PN 862223-03R)	12/27/2021	Intuitive-02047561	Intuitive-02047647	
DX1771.31	K214095 - Appendix C3: Reliability Verification Protocol for Force Bipolar (PN862225-02P)	12/27/2021	Intuitive-02048248	Intuitive-02048281	
DX1771.32	K214095 - Appendix C4: Reliability Verification Report for Force Bipolar (PN 862225-04R)	12/27/2021	Intuitive-02051749	Intuitive-02051859	
DX1771.33	K214095 - Appendix C5: Reliability Verification Protocol for Large Needle Driver (PN 862211-04P)	12/27/2021	Intuitive-02048418	Intuitive-02048448	

Compilation of Select SIS Customer Contracts.					
Def.'s Temporary Exhibit No.	Description	Date	Beg Bates	End Bates	Objections
DX1772.01	Rigid/Semi-Rigid Endoscope Repair Agreement between Surgical Instrument Service Company and Banner Health System	01/15/1999	SIS298505	SIS298508	
DX1772.02	Surgical Instrument Repair/Restore Agreement between Surgical Instrument Service Company and Advocate Trinity Hospital	06/01/2001	SIS343473	SIS343474	
DX1772.03	Services Agreement between Surgical Instrument Service Company and Banner Health System	05/01/2002	SIS100789	SIS100807	
DX1772.04	Rigid/Semi-Rigid Endoscope Repair Agreement between Surgical	05/01/2002	SIS100808	SIS10081	
DX1772.05	No-Risk Service Agreement between Surgical Instrument Service	09/05/2007	SIS006291	SIS006307	
DX1772.06	No-Risk Service Agreement between Surgical Instrument Service Company and Advocate Health and Hospitals Corp. DBA Advocate Trinity Hospital	02/27/2008	SIS101274	SIS101290	
DX1772.07	Service and Repair of Medical Devices Agreement between Surgical Instrument Service Company and Alexian Brothers Corporate Materials Management	01/01/2009	SIS004867	SIS004868	
DX1772.08	Capitated Agreement for the Service and Repair of Medical Devices between Surgical Instrument Service Company and Advocate Lutheran General Hospital	01/01/2009	SIS004892	SIS004894	
DX1772.09	Capitated Agreement for the Service and Repair of Flexible Endoscopes between Surgical Instrument Service Company and Advocate Health and Hospital Corp. DBA Advocate Lutheran General Hospital	01/01/2009	SIS005993	SIS005997	
DX1772.10	Flexible Endoscope Service Agreement between Surgical Instrument Service Company and Advocate Lutheran General Hospital	01/01/2009	SIS101065	SIS101071	
DX1772.11	Capitated Agreement for the Service and Repair of Medical Devices between Surgical Instrument Service Company and Advocate Lutheran General Hospital	01/01/2009	SIS101072	SIS101074	
DX1772.12	Capitated Agreement for the Service and Repair of Flexible Endoscopes (GI) between Surgical Instrument Service Company and Advocate Health and Hospital Corp. DBA Advocate Lutheran General Hospital	01/01/2009	SIS101078	SIS101082	
DX1772.13	Capitated Agreement for the Service and Repair of Flexible Endoscopes between Surgical Instrument Service Company and Advocate Trinity Hospital	02/01/2009	SIS005880	SIS005881	
DX1772.14	Capitated Agreement for the Service and Repair of Flexible Endoscopes (GI) between Surgical Instrument Service Company and Advocate Illinois Masonic Medical Center	02/01/2009	SIS101050	SIS101052	
DX1772.15	Capitated Agreement for the Service and Repair of Flexible Endoscopes (GI) between Surgical Instrument Service Company and Advocate Health and Hospital Corp. DBA Advocate Trinity Hospital	02/01/2009	SIS101291	SIS101295	
DX1772.16	Capitated Agreement for the Service and Repair of Flexible Endoscopes (GI) between Surgical Instrument Service Company and Advocate Health and Hospital Corp. DBA Advocate Christ Hospital	03/01/2009	SIS100823	SIS100827	
DX1772.17	Capitated Agreement for the Service and Repair of Flexible Endoscopes (GI) between Surgical Instrument Service Company and Advocate Health and Hospital Corp. DBA Advocate Illinois Masonic Hospital	03/15/2009	SIS101083	SIS101087	
DX1772.18	Capitated Agreement for the Service and Repair of Flexible Endoscopes (GI) between Surgical Instrument Service Company and Advocate Health and Hospital Corp. DBA Advocate Christ Hospital	04/01/2010	SIS122139	SIS122143	
DX1772.19	Capitated Agreement for the Service and Repair of Flexible Endoscopes (GI) between Surgical Instrument Service Company and Advocate Health and Hospital Corp. DBA Advocate Christ Hospital	04/10/2010	SIS100828	SIS100832	
DX1772.20	Agreement for the Service and Repair of Medical Equipment and Devices between Surgical Instrument Service Company and Providence Health & Services	10/01/2010	SIS004789	SIS004790	
DX1772.21	Agreement for the Service and Repair of Medical Equipment and Devices between Surgical Instrument Service Company and Providence Health & Services	10/01/2010	SIS006070	SIS006073	
DX1772.22	Capitated Agreement for the Service and Repair of Flexible Endoscopes (GI) between Surgical Instrument Service Company and Advocate Health and Hospital Corp. DBA Advocate Trinity Hospital	03/01/2011	SIS006588	SIS006592	
DX1772.23	Capitated Agreement for the Service and Repair of Flexible Endoscopes (GI) between Surgical Instrument Service Company and Advocate Health and Hospital Corp. DBA Advocate Christ Hospital	05/01/2011	SIS006564	SIS006569	
DX1772.24	Capitated Agreement for the Service and Repair of Flexible Endoscopes between Surgical Instrument Service Company and Advocate Trinity Hospital	03/01/2012	SIS008931	SIS008932	
DX1772.25	Service Agreement between Surgical Instrument Service Company and Advocate Health Care	07/01/2012	SIS006447	SIS006456	
DX1772.26	Service Agreement between Surgical Instrument Service Company and Advocate Health Care	07/02/2012	SIS006514	SIS006524	
DX1772.27	Standard Agreement between Yankee Alliance, LLC and Surgical Instrument Service Company	11/01/2012	SIS143367	SIS143374	

DX1772.28	Capitated Agreement for the Service and Repair of General and Specialty Surgical Instruments between Surgical Instrument Service Company and Alexian Brothers Medical Center	02/01/2013	SIS008910	SIS008912	
DX1772.29	Pricing Agreement for the Service and Repair of Medical Equipment and Devices between Surgical Instrument Service Company and Alexian Brothers Medical Center	02/02/2013	SIS008916	SIS008917	
DX1772.30	Service Agreement between Surgical Instrument Service Company and Banner Health	03/01/2013	SIS008846	SIS008855	
DX1772.31	Products and Services Agreement between Surgical Instrument Service Company and Kaiser Foundation Health Plan of the Northwest	04/01/2013	SIS040537	SIS040566	
DX1772.32	Products and Services Agreement between Surgical Instrument Service Company and Kaiser Foundation Health Plan of the Northwest	04/02/2013	SIS033812	SIS033840	
DX1772.33	Agreement for the Service and Repair of Flexible Endoscopes between Surgical Instrument Service Company and Banner Health Urology Clinic	06/01/2013	SIS008842	SIS008843	
DX1772.34	Agreement for the Service and Repair of Flexible Endoscopes between Surgical Instrument Service Company and Banner Health Urology Clinic	06/02/2013	SIS008844	SIS008845	
DX1772.35	Capitated Agreement for the Service and Repair of Flexible Endoscopes between Surgical Instrument Service Company and Advocate Good Samaritan Hospital	09/01/2013	SIS032394	SIS032397	
DX1772.36	Products and Services Agreement between Surgical Instrument Service Company and Kaiser Foundation Health Plan of the Northwest	10/11/2013	SIS091395	SIS091421	
DX1772.37	Capitated Agreement for the Repair, Maintenance and Refurbishment of Medical Devices and Instrumentation between Surgical Instrument Service Company and Johnson Memorial Hospital, Advanced Wound Center, and Surgery Center	02/01/2014	SIS080681	SIS080685	
DX1772.38	Capitated Agreement for the Repair, Maintenance and Refurbishment of Medical Devices and Instrumentation between Surgical Instrument Service Company and Johnson Memorial Hospital, Advanced Wound Center, and Surgery Center	02/01/2014	SIS330343	SIS330346	
DX1772.39	Capitated Agreement for the Service and Repair of Surgical Equipment, Devices, and Instrumentation between Surgical Instrument Service Company and Winchester Hospital	03/01/2015	SIS086962	SIS086968	
DX1772.40	Agreement for the Service and Repair of Endoscopic Video Equipment between Surgical Instrument Services and Advocate Good Samaritan Hospital	01/01/2016	SIS040777	SIS040781	
DX1772.41	Supplier Services Agreement for Instrument Repair between Vizient Supply, LLC and Surgical Instrument Service Company	09/01/2016	SIS330591	SIS330634	
DX1772.42	Fixed Spend Agreement for the Service and Repair of Medical Equipment and Devices between Surgical Instrument Service Company and Lahey Hospital & Medical Center	02/01/2017	SIS112474	SIS112482	
DX1772.43	Fixed Spend Agreement for the Service and Repair of Medical Equipment Devices between Surgical Instrument Service Company and Lahey Hospital & Medical Center	03/01/2017	SIS076346	SIS076354	
DX1772.44	Agreement for the Service and Repair of Medical Equipment and Devices between Surgical Instrument Service Company and Lahey Clinic Hospital	03/10/2017	SIS082407	SIS082407	
DX1772.45	Fixed Spend Agreement for the Service and Repair of Medical Equipment and Devices between Surgical Instrument Service Company and Lahey Clinic Hospital	04/01/2017	SIS033794	SIS033802	
DX1772.46	Fixed Spend Agreement for the Service and Repair of Medical Equipment and Devices between Surgical Instrument Service Company and Lahey Clinic Hospital	04/01/2017	SIS327546	SIS327558	
DX1772.47	Fixed Spend Agreement for the Service and Repair of Medical Equipment and Devices Addendum D between Surgical Instrument Service Company and Lahey Clinic Hospital	07/01/2017	SIS076345	SIS076345	
DX1772.48	Fixed Spend Agreement for the Service and Repair of Medical Equipment and Devices Addendum D between Surgical Instrument Service Company and Lahey Clinic Hospital	09/01/2017	SIS033793	SIS033793	
DX1772.49	Agreement for the Service and Repair of Medical Equipment and Devices between Surgical Instrument Service Company and Lahey Hospital & Medical Center	09/01/2017	SIS075313	SIS075342	
DX1772.50	Flexible Endoscope Service Agreement between Surgical Instrument Service Company and Advocate Health and Hospitals Corp.	11/01/2017	SIS100774	SIS100788	
DX1772.51	Agreement for the Service and Repair of Medical Equipment and Devices Surgical Instrument Service Company between Lahey Hospital & Medical Center	11/01/2017	SIS330566	SIS330586	
DX1772.52	Fixed Spend Agreement for the Service and Repair of Handheld Surgical Instruments and Devices between Surgical Instrument Company and Kaiser Permanente San Diego Medical Center	04/01/2018	SIS336220	SIS336226	
DX1772.53	Fixed Spend Agreement for the Service and Repair of Handheld Surgical Instruments and Devices between Surgical Instrument Company and Kaiser Permanente Zion Medical Center	01/01/2019	SIS064623	SIS064632	

DX1772.54	Amendment to the Yankee Alliance Supply Chain Solutions, LLC's and Yankee Alliance, LLC's Standard Agreement between Yankee Alliance Supply Chain Solutions, LLC and Yankee Alliance, LLC and Surgical Instrument Service Company Inc.	01/01/2019	SIS093184	SIS093184	
DX1772.55	Master Services Agreement between Piedmont Healthcare, Inc. and Surgical Instrument Service Company	06/01/2019	SIS063463	SIS063492	
DX1772.56	Master Services Agreement between Surgical Instrument Service Company and Methodist Hospital of Southern California	09/01/2019	SIS009856	SIS009870	
DX1772.57	Master Services Agreement between Surgical Instrument Services Company and Methodist Hospital of Southern California	09/01/2019	SIS038509	SIS038522	
DX1772.58	Master Services Agreement between Surgical Instrument Service Company and Methodist Hospital of Southern California	09/01/2019	SIS070480	SIS070494	
DX1772.59	Master Services Agreement between Surgical Instrument Service Company and Methodist Hospital of Southern California	09/01/2019	SIS071064	SIS071080	
DX1772.60	Master Services Agreement between Surgical Instrument Service Company and Methodist Hospital of Southern California	09/01/2019	SIS106403	SIS106418	
DX1772.61	Master Services Agreement between Surgical Instrument Service Company and Methodist Hospital of Southern California	09/01/2019	SIS106422	SIS106435	
DX1772.62	Master Services Agreement between Surgical Instrument Service Company and Methodist Hospital of Southern California	09/01/2019	SIS106439	SIS106453	
DX1772.63	Amendment to Agreement between Vizient Supply, LLC and Surgical Instrument Service Company	09/15/2019	SIS047433	SIS047435	
DX1772.64	Statement of Work One between Surgical Instrument Service Company and Legacy Health	11/01/2019	SIS010981	SIS010983	
DX1772.65	Statement of Work One between Surgical Instrument Service Company and Legacy Health	11/01/2019	SIS038186	SIS038188	
DX1772.66	Master Services Agreement between Surgical Instrument Service Company and Legacy Health	01/01/2020	SIS330378	SIS330413	
DX1772.67	Statement of Work Three-Fixed Cost Flexible Endoscope Repairs between Surgical Instrument Service Company and Legacy Health	03/01/2020	SIS037925	SIS037928	
DX1772.68	Statement of Work -Fixed Cost Surgical Device and Instrument Services between Surgical Instrument Service Company and Salinas Valley Memorial Healthcare System	05/01/2020	SIS097220	SIS097231	
DX1772.69	Master Services Agreement between Surgical Instrument Service Company and Salinas Valley Memorial Healthcare System	05/01/2020	SIS097232	SIS097244	
DX1772.70	Supplier Services Agreement for Third Party Instrument and Scope Repair between Vizient Supply, LLC and Surgical Instrument Service Co.	08/01/2020	SIS169233	SIS169280	
DX1772.71	Vizient Amendment to Agreement with SIS	11/15/2020	SIS116933	SIS116940	
DX1772.72	Exhibit 1 Palos Community Hospital Statement of Work #1 Fixed Cost Instrument Maintenance and Device Repair between Surgical Instrument Service Company and Northwestern Memorial HealthCare	04/01/2021	SIS029675	SIS029693	
DX1772.73	Master Services Agreement between Surgical Instrument Service Company and Northwestern Memorial HealthCare	04/01/2021	SIS045720	SIS045736	
DX1772.74	Statement of Work Two Fixed Cost Endoscope Repair and Maintenance Silverton GI Department between Surgical Instrument Service Company and Legacy Health	05/01/2021	SIS045336	SIS045339	
DX1772.75	Statement of Work Three Fixed Cost Endoscope Repair and Maintenance Good Samaritan GI Department between Surgical Instrument Service Company and Legacy Health	05/01/2021	SIS045341	SIS045344	
DX1772.76	Statement of Work Four Pay Per Service Repair and Maintenance between Surgical Instrument Service Company and Legacy Health	05/01/2021	SIS045346	SIS045350	
DX1772.77	Master Services Agreement between Surgical Instrument Service Company and Legacy Health	05/01/2021	SIS047556	SIS047570	
DX1772.78	Statement of Work One Fixed Cost Instrument Maintenance between Surgical Instrument Service Company and Legacy Health	05/01/2021	SIS069048	SIS069051	
DX1772.79	Statement of Work Four Fixed Cost Endoscope Repair and Maintenance Meridian Park GI Department between Surgical Instrument Service Company and Legacy Health	06/01/2021	SIS045117	SIS045121	
DX1772.80	Amendment to Agreement between Vizient Supply, LLC and Surgical Instrument Service Company	06/01/2021	SIS045231	SIS045232	
DX1772.81	Master Services Agreement between Surgical Instrument Service Company and Lahey Hospital & Medical Device Center	07/22/2021	SIS044362	SIS044398	
DX1772.82	Master Services Agreement between Surgical Instrument Service Company and Lahey Hospital & Medical Device Center	07/22/2021	SIS044418	SIS044443	
DX1772.83	Amendment to Agreement between Vizient Supply, LLC and Surgical Instrument Service Company	10/08/2021	SIS075744	SIS075746	
DX1772.84	Standard Agreement Contract # - YA-OR-146 between Yankee Alliance Supply Chain Solutions, LLC and Surgical Instrument Service Company	02/01/2022	SIS163317	SIS163341	
DX1772.85	Statement of Work One between Surgical Instrument Service Company and Salinas Valley Memorial Healthcare System	n/a	SIS032556	SIS032558	
DX1772.86	Agreement for the Service and Repair of Medical Equipment and Devices between Surgical Instrument Service Company and Advocate Good Samaritan Hospital	n/a	SIS037016	SIS037021	

DX1772.87	Yankee Alliance Members Capitated-Guaranteed Savings Program Contract #YA-MM-014 between Surgical Instrument Service Company and Yankee Alliance Members	n/a	SIS064237	SIS064237	
DX1772.88	Agreement for the Service and Repair of Medical Equipment and Devices between Surgical Instrument Service Company and Advocate Good Samaritan Hospital	n/a	SIS080643	SIS080648	
DX1772.89	Agreement for the Service and Repair of Medical Equipment and Devices between Surgical Instrument Service Company and Advocate Good Samaritan Hospital	n/a	SIS080650	SIS080655	
DX1772.90	Agreement for the Service and Repair of Medical Equipment and Devices between Surgical Instrument Service Company and Advocate Good Samaritan Hospital	n/a	SIS080660	SIS080665	
DX1772.91	Statement of Work: Fixed Cost Device Repairs between Surgical Instrument Service Company and Salinas Valley Memorial Healthcare System	n/a	SIS081069	SIS081083	
DX1772.92	Statement of Work One Pay Per Service Repair and Maintenance between Surgical Instrument Repair Company and Lahey Hospital & Medical Center	n/a	SIS126987	SIS126992	
DX1772.93	Service and Repair of Medical Equipment and Devices between Surgical Instrument Service Company and Advocate Good Samaritan Hospital	n/a	SIS335982	SIS335987	
DX1772.94	Statement of Work One Pay Per Service Repair and Maintenance between Surgical Instrument Repair Company and Lahey Hospital & Medical Center	n/a	SIS044581	SIS044585	

Compilation of SIS to Vizient Line-Item Sales Detail Reports.					
Def.'s Temporary Exhibit No.	Description	Date	BegBates	EndBates	Objections
DX1773.01	09012016 SIS TO Vizient.xlsx	10/2016	SIS280464	SIS280464	
DX1773.02	11012016 SIS TO Vizient.xlsx	12/2016	SIS333117	SIS333117	
DX1773.03	01012017 SIS TO Vizient.xlsx	2/2017	SIS333128	SIS333128	
DX1773.04	02012017 SIS TO Vizient.xlsx	3/2017	SIS333126	SIS333126	
DX1773.05	03012017 SIS TO Vizient.xlsx	4/2017	SIS333133	SIS333133	
DX1773.06	04012017 SIS TO Vizient.xlsx	5/2017	SIS333121	SIS333121	

Exhibit 2

Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc.
No. 3:21-cv-03496-AMO

Intuitive Surgical, Inc.’s Preliminary Witness List

Pursuant to the parties’ agreement, Intuitive Surgical, Inc. (“Intuitive” or “Defendant”) hereby serves its preliminary list of witnesses it intends to call or may call at trial in the above-captioned matter. This list is preliminary and Intuitive reserves the right to modify, supplement, or otherwise amend its witness list, including to add or withdraw any witness that Surgical Instrument Service Company, Inc. (“SIS”) identifies on its witness list or fails to identify on its witness list, or to add or withdraw any witness that SIS calls during trial, and/or to rely on any deposition testimony designated by SIS in whole or in part.

Intuitive’s inclusion of any witness on this preliminary witness list does not waive any objections Intuitive may have to the introduction of that witness’s testimony if offered by SIS, and is without prejudice to Intuitive’s right to move to strike witnesses from SIS’s list who were not properly disclosed.

The descriptions of testimony listed below are not intended to be exhaustive and Intuitive reserves the right to amend these descriptions of testimony and/or present testimony from these witnesses on topics that are not specifically listed below, or testimony that is responsive to testimony presented during SIS’s case-in-chief. The estimates of time listed below are estimates only; Intuitive reserves the right to present testimony from these witnesses that exceeds the estimates of time listed below.

I. Intuitive Fact Witnesses

Name	Affiliation	Presentation	Description of Testimony	Time
Ron Bair	Intuitive	Live	The use of da Vinci surgical systems in the field, Intuitive’s response to EndoWrists reset by third parties, and the feasibility of refurbishing EndoWrist instruments.	1 hour or less
Myriam Curet	Intuitive	Live	The design, features, and performance of the da Vinci surgical system, and her role and responsibilities as Intuitive’s Chief Medical Officer. Ms. Curet may also testify regarding her personal experience using the da Vinci system as a surgeon, her	1-2 hours

			personal experience using open and laparoscopic surgical techniques, and certain communications with regulators and/or customers.	
Bob DeSantis	Intuitive	Live	The development, design, and testing of EndoWrist instruments, the EndoWrist Extended Use program and/or the feasibility of refurbishing EndoWrist instruments, and EndoWrists reset by third parties.	1 hour or less
Grant Duque	Intuitive	Live	The development, design, and testing of EndoWrist instruments (including but not limited to the development, design, and testing of the X/Xi EndoWrist instruments), and the EndoWrist Extended Use program.	1-2 hours
Mark Johnson	Former Intuitive	Live or by deposition	Regulatory issues and communications with regulators.	1 hour or less
Anthony McGrogan	Intuitive	Live	The development, design, and testing of EndoWrist instruments (including but not limited to the development, design, and testing of the X/Xi EndoWrist instruments), the EndoWrist Extended Use program and/or the feasibility of refurbishing EndoWrist instruments, and EndoWrists reset by third parties.	1-2 hours
Maggie Nixon	Former Intuitive	Live or by deposition	The development, design, and testing of EndoWrist instruments.	1 hour or less
Dave Rosa	Intuitive	Live	All relevant aspects of Intuitive's business, including the development, design, and testing of the da Vinci surgical system and EndoWrist instruments; Intuitive's efforts to compete and sources of competition; Intuitive's research and development efforts; Intuitive's marketing, sales, and pricing; regulatory	3-4 hours

			affairs; Intuitive's Extended Use program and the feasibility of refurbishing EndoWrist instruments; and EndoWrists reset by third parties.	
Jeff Smith	Intuitive	Live	The development, design, and testing of the da Vinci surgical system and EndoWrist instruments	1-2 hours
Glenn Vavoso	Intuitive	Live	Intuitive's marketing, sales, and pricing, and Intuitive's efforts to compete and sources of competition.	1-2 hours

II. SIS Fact Witnesses

Name	Affiliation	Presentation	Summary	Time
Keith Johnson	SIS	Live	If not called by SIS, Mr. Johnson will be called to testify regarding all aspects of SIS's claims and defenses.	3-4 hours
Gregory Posdal	SIS	Live	If not called by SIS, Mr. Posdal will be called to testify regarding all aspects of SIS's claims and defenses.	3-4 hours

III. Non-Party Fact Witnesses

Name	Affiliation	Presentation	Description of Testimony	Time
Ronald Arkin	Arkin Consulting	By deposition	Competition in the alleged market for the repair and replacement of EndoWrist instruments and regulatory issues.	1 hour or less

Rafal Chudzik	Alliance/Iconocare	By deposition	Competition in the alleged market for the repair and replacement of EndoWrist instruments and regulatory issues.	1 hour or less
Ricardo Estape	Larkin	By deposition	The da Vinci surgical system from the perspective of a surgeon, and EndoWrists reset or reprogrammed by third parties.	1 hour or less
Rick Ferreira	Alliance/Iconocare	By deposition	Competition in the alleged market for the repair and replacement of EndoWrist instruments and regulatory issues.	1-2 hours
John Francis	Franciscan	By deposition	The da Vinci surgical system from the perspective of a surgeon, and EndoWrists reset or reprogrammed by third parties.	1 hour or less
Dipien Maun	Franciscan	By deposition	The da Vinci surgical system from the perspective of a surgeon, and EndoWrists reset or reprogrammed by third parties.	1 hour or less
Liz Nolan	Valley Medical	By deposition	Marketing of da Vinci surgery.	1 hour or less
Paul Plomin	Franciscan	By deposition	Hospital purchases of da Vinci surgical systems and EndoWrist instruments.	1 hour or less
Michael Shepherd	Franciscan	By deposition	Marketing of da Vinci surgery.	1 hour or less
John Wagner	Valley Medical	By deposition	Hospital purchases of da Vinci systems and EndoWrist instruments.	1 hour or less

Chris Gibson	Rebotix	By deposition	If not called by SIS, Mr. Gibson may be called to authenticate and lay the foundation for the admission of documents, if necessary.	1 hour or less
Stan Hamilton	Rebotix	By deposition	If not called by SIS, Mr. Hamilton may be called to authenticate and lay the foundation for the admission of documents, if necessary.	1 hour or less
David Mixner	Rebotix	By deposition	If not called by SIS, Mr. Mixner may be called to authenticate and lay the foundation for the admission of documents, if necessary.	1 hour or less
Joe Morrison	Rebotix	By deposition	If not called by SIS, Mr. Morrison may be called to authenticate and lay the foundation for the admission of documents, if necessary.	1 hour or less
Glenn Papit	Rebotix	By deposition	If not called by SIS, Mr. Papit may be called to authenticate and lay the foundation for the admission of documents, if necessary.	1 hour or less
West Gordon	Restore	By deposition	If not called by SIS, Mr. Gordon may be called to authenticate and lay the foundation for the admission of documents, if necessary.	1 hour or less
Kevin May	Restore	By deposition	If not called by SIS, Mr. May may be called to authenticate and lay the foundation for the admission of documents, if necessary.	1 hour or less
Clif Parker	Restore	By deposition	If not called by SIS, Mr. Parker may be called to authenticate and lay the foundation for the admission of documents, if necessary.	1 hour or less

IV. Expert Witnesses

Name	Affiliation	Presentation	Description of Testimony	Time
Christy Foreman	Biologics Consulting Group	Live	Ms. Foreman will testify to matters disclosed in her expert report serviced in this case, and in response to testimony from SIS's experts.	1-2 hours
Jason Goodwin	Sacramento City College	Live	Prof. Goodwin will testify to matters disclosed in his expert report served in this case, and in response to testimony from SIS's experts.	1-2 hours
Robert Howe	Harvard University	Live	Dr. Howe will testify to matters disclosed in his expert reports served in this case, and in response to testimony from SIS's experts.	2-3 hours
Paul Martin	Harbor Labs, Inc.	Live	Mr. Martin will testify to matters disclosed in his expert report served in this case, and in response to testimony from SIS's experts.	1-2 hours
Maxwell Meng	University of California, San Francisco	Live	Dr. Meng will testify to matters disclosed in his expert report served in this case, and in response to testimony from SIS's experts.	1-2 hours
Loren Smith	University of Virginia	Live	Prof. Smith will testify to matters disclosed in his expert reports in this case, and in response to testimony from SIS's experts.	3-4 hours

Exhibit 3

ATTACHMENT 37

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA**

SURGICAL INSTRUMENT SERVICE COMPANY,
INC.,

Plaintiff/Counterclaim Defendant,

v.

INTUITIVE SURGICAL, INC.,

Defendant/Counterclaim Plaintiff.

Case No. 3:21-cv-03496-VC

EXPERT REPORT OF CHRISTY FOREMAN, MBE

Senior Consultant, Biologics Consulting Group

January 18, 2023

This report contains confidential material and is subject to the order governing the production, exchange and filing of confidential information in this matter.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

Table of Contents

I.	Qualifications	1
II.	Assignment, Summary of Opinions and Materials Considered	5
III.	Medical Device Regulatory Overview	8
A.	FDA Regulatory Authority	8
1.	Statutory Authority	8
2.	Regulation	9
3.	Guidance Documents.....	10
B.	Medical Device Classification.....	12
C.	Premarket (510(k)) Notification.....	17
1.	Background on 510(k) Notification	18
2.	Substantial Equivalence	20
3.	Deficiency Letters.....	23
IV.	Opinions and Bases for Opinions	23
A.	Opinion 1 – Remanufacturing medical devices is a manufacturing activity, which is subject to FDA regulatory requirements, including premarket notification, registration, recall, medical device reporting, unique device identification, and postmarket surveillance among others.	24
B.	Opinion 2 – EndoWrist instruments were cleared by FDA as limited use devices, and efforts to remove or extend the usage limitation by companies other than the original equipment manufacturer (OEM) constitute remanufacturing activities.....	27
1.	FDA cleared EndoWrist instruments as limited use devices.	27
2.	FDA has acknowledged the limited use nature of EndoWrist instruments in communications to third parties.....	47
3.	Objective and publicly available evidence demonstrates that FDA has determined that removing or extending the usage limitation	

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

on EndoWrist instruments is a remanufacturing activity, and as such, it requires 510(k) clearance.	48
4. Third parties engaging in extending or resetting the lives of EndoWrist instruments are remanufacturers under existing FDA regulation. Therefore, they were required to obtain 510(k) clearance.	55
C. Opinion 3 – FDA communicated to certain third parties that their activities constituted remanufacturing.	68
D. Opinion 4 – Intuitive has acted in accordance with FDA’s requirements for the marketing and sale of its devices and has not unreasonably interpreted FDA’s existing regulations and guidance.	75
1. Intuitive’s marketing and sale of EndoWrist instruments with usage limits is consistent with FDA’s regulatory requirements.	75
2. Intuitive’s cybersecurity measures are consistent with FDA expectations for devices that are vulnerable to cybersecurity threats.	78
3. Intuitive’s internal conduct does not contradict applicable FDA regulations and guidance, nor does it negate the duty of third-party companies to comply with existing FDA regulations and guidance.	81
V. Conclusion.....	86
Appendices.....	88
Appendix A – Curriculum Vitae of Christy Foreman	89
Appendix B – Materials Considered.....	94
Appendix C - QSM and NAY Premarket Submissions	102

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

I. Qualifications

1. I graduated from The Catholic University of America with Bachelor's and Master's degrees in Biomedical Engineering. While I was pursuing my undergraduate degree, I began working at the Naval Medical Research Institute (NMRI). There, I supported the research activities designed to evaluate the physiologic effects of non-freezing cold injury as well as the research activities evaluating short term memory decrements in cold weather operations in humans and animals. I worked there for a total of seven years before I departed to work for the US Food and Drug Administration (FDA) in 1996.

2. I started at FDA as a reviewer in the Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), Division of Cardiovascular, Respiratory, and Neurological Devices in the Anesthesiology and Defibrillator Devices Group. While working as a reviewer, I reviewed a wide variety of devices including ventilators, hyperbaric chambers, multi-parameter monitors, pulse oximeters, automated external defibrillators and implantable defibrillators, including the biventricular (cardiac resynchronization therapy) defibrillators designed to treat heart failure, a novel, brand-new indication at the time.

3. As a lead reviewer, I reviewed hundreds of 510(k) submissions, Investigational Device Exemption (IDE) Submissions, and Premarket Approval (PMA) Application Submissions. I also served as a signatory reviewer, reviewing the work of others as a technical expert. I was appointed as the FDA representative on voluntary consensus standards such as the National Fire Protection Association (NFPA) standard on Hyperbaric and Hypobaric Facilities, American Society of Mechanical Engineers (ASME) standard on Pressure Vessels for Human Occupancy, and the American Society for Testing and Materials (ASTM) G175 Standard

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Pressure Regulators Used for Medical and Emergency Applications. These standards are developed in conjunction with industry, academia, and health care providers to set forth requirements for safe design practices as well as test methods for evaluating medical device designs.

4. In 2000, I was selected for a highly competitive FDA Leadership Development Program. Over the course of the program, in addition to training opportunities, I completed several detail assignments further expanding my FDA knowledge base. The detail assignments included a branch chief position in the Minnesota District Office, where I oversaw the Import Operation activities as well as participated in inspections of drug, device, and food manufacturers as well as bioresearch monitoring inspections. I also had an assignment at Health Canada in the Medical Devices Bureau to compare and contrast the different regulatory processes between the US and Canada. I also completed an assignment in the Office of Science, Communication and Coordination in the Office of the Commissioner where I served as the executive secretary for the Science Board, an advisory committee designed to advise the Commissioner of various scientific topics.

5. My final detail assignment was in CDRH's Office of Compliance (OC) in the Division of Enforcement B as the Deputy Division Director. The division was responsible for the compliance oversight of cardiovascular, neurology, orthopedic, physical medicine, anesthesiology, and radiology devices, as well as electronic products. This detail lasted 10 months until I accepted a permanent position as the branch chief for the Orthopedic, Physical Medicine, and Anesthesiology Devices Branch in OC in 2001. After a year in the position, I was

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

selected in 2002 for the permanent Deputy Division Director position in OC where I had previously served on detail.

6. While working in OC, I was responsible for the oversight of inspection reviews, PMA quality system reviews, 30-day notice reviews, recalls, warning letters, seizures, injunctions, and civil money penalties. In this position, I not only oversaw the review activities, but developed policy in these areas as well. I routinely provided training for industry at AdvaMed workshops, AAMI Quality System Training Courses as well as participated in numerous conferences where I was invited to speak. I was responsible for overseeing many enforcement actions including civil money penalties for mammography facilities, a seizure, and injunction for a tissue-based heart valve and valve conduit as well as injunctions for an automated external defibrillator, an orthopedic implant, and x-ray surgical imaging systems. I also served as an FDA expert witness in a criminal case against an implantable defibrillator and pacemaker manufacturer.

7. In 2008, I returned to ODE as the Deputy Office Director for Science and Engineering reviews. In this role I served as the chief scientific officer for ODE and oversaw the regulatory policies associated with 510(k), PMA, HDE, IDE, de novo and 513(g) programs as well as combination products as well as provided office- level review and sign-off for guidance documents, de novo submissions and 513(g) submissions. In this role, the area of oversight included surgical devices including surgical robots.

8. In 2010, I began serving as the Office Director for ODE. In that role, I oversaw a staff of 500+ scientists and clinicians conducting the regulatory review of applications including 510(k)s, PMAs, IDEs, HDEs, pre- submissions, Product Development

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

Protocols, De Novos and 513(g)s, as well as consults for combination products in NDAs and BLAs and decided all office level appeals. I provided the final sign-off for first of a kind Premarket Approval Applications. I also participated in user fee negotiations with industry, implemented the user fee commitments into the regulatory review programs and implemented new legislation (FDASIA). In this role, the area of oversight included surgical devices including surgical robots.

9. In 2014, I joined the FDA's newest Center, the Center for Tobacco Products to help develop new regulations and regulatory programs to help implement the Family Smoking Prevention and Tobacco Control Act (FSPTCA), also known as the Tobacco Control Act which gave FDA the authority to regulate tobacco. The law was largely based on the medical device provisions of the Federal Food, Drug, and Cosmetic Act. I was recruited for my significant experience with the medical device programs. There, I worked on foundation regulations such as the tobacco product manufacturing regulation as well as implemented new enforcement programs such as the No-Tobacco-Sale Order (NTSO) program. I participated in inspections of tobacco product manufacturers as a subject matter expert. I also developed and oversaw enforcement actions for egregious violators of the Tobacco Control Act. I was involved in the pursuit of thousands of civil money penalty cases and over 100 NTSO cases during my time at CTP. My experience with these cases affords my expertise in the type and quality of evidence that is needed to support an FDA enforcement action.

10. In 2018, I left CTP to join Biologics Consulting as a Senior Consultant. In my role as a Senior Consultant, I advise clients on short and long term regulatory strategies for medical devices and combination products, assist in the development of Quality Systems,

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

prepare medical device regulatory submissions, including 510(k)s, PMAs, HDEs, RFDs, 513(g)s, pre-submissions, and IDEs, represent clients in interactions with FDA, assist clients in the preparation for Advisory Panel meetings and provide in-house training on FDA regulatory issues and new policy developments. I also provide expert services to litigants.

11. Additionally, I am an adjunct lecturer at The Catholic University of America, where I teach a graduate level course entitled Medical Device Design and Regulation in the Biomedical Engineering Department.

12. A copy of my curriculum vitae is attached as Appendix A.

II. Assignment, Summary of Opinions and Materials Considered

13. I have been retained by defendant Intuitive Surgical, Inc. ("Intuitive") to provide my expert opinions on certain FDA-related matters in this litigation.

14. The professional fee charged for my consulting time by my employer, Biologics Consulting, is \$525 per hour. I am a salaried employee of Biologics Consulting. My compensation is not dependent on my opinions in, or the outcome of, this litigation. I have testified as an expert in the preceding four years in the following matters: *Tonya Brand v. Cook Medical, Inc.*, Deposition: July 2018; Trial: January 2019, Southern District of Indiana No. 1:14-cv-06018-RLY-TAB; *Karen Richards v. Ethicon, Inc. and Johnson & Johnson*, Trial: October 2022, Eastern District of Texas No. 5:21-cv-92-RWS; *Selex Galileo, Inc. v. Nomir Medical Technologies, Inc.*, International Center for Dispute Resolution, No. 01-17-0003-0930.

15. My opinions and analyses in this report are based on my review and evaluation of the materials listed in Appendix B. In addition, my opinions are based on my knowledge and experience of FDA regulation of medical devices, including all applicable laws,

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

regulations, guidance, and policies. I reviewed and assessed the documents in a similar manner as I would have while employed at the FDA and as I do now as a medical device consultant. I did not rely on any commercial, confidential, or trade secret information obtained during my employment at FDA in forming my opinions.

16. Based on the analyses developed in the body of my report, I conclude:
 - a. Remanufacturing medical devices is a manufacturing activity, which is subject to FDA regulatory requirements, including premarket notification, registration, recall, medical device reporting, unique device identification, and postmarket surveillance among others.
 - b. EndoWrist instruments were cleared by FDA as limited use devices, and efforts to remove or extend the usage limitation by companies other than the original equipment manufacturer (OEM) constitute remanufacturing activities.
 - i. FDA cleared EndoWrist instruments as limited-use devices.
 - ii. FDA has acknowledged the limited use nature of EndoWrist instruments in communications to third parties.
 - iii. Objective and publicly available evidence demonstrates that FDA has determined that removing or extending the usage limitation on EndoWrist instruments is a manufacturing activity, and as such, it requires 510(k) clearance.
 1. FDA has classified remanufactured EndoWrists as Class II devices, assigned them a unique procode, and indicated that they require 510(k) clearance.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

2. Congress also reached the same conclusion for a similar industry and activity – reprocessing – and amended FDA's governing statute to define premarket requirements for the reprocessors of devices labeled for single use.
- iv. Third parties engaging in extending or resetting the lives of EndoWrist instruments are remanufacturers under existing FDA regulation.

Therefore, they were required to obtain 510(k) clearance.

1. The activities that the third parties undertake to extend the usage limits significantly change the performance specifications of EndoWrist instruments.
 2. The activities that the third parties undertake to extend the usage limits significantly change the safety specifications of EndoWrist instruments.
 3. The third parties are introducing new devices into interstate commerce, which makes their activity subject to FDA requirements.
 4. The third parties' arguments that they are not remanufacturers are incorrect.
- c. FDA communicated to certain third parties that their activities constituted remanufacturing.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

- d. Intuitive has acted in accordance with FDA's requirements for the marketing and sale of its devices and has not unreasonably interpreted FDA's existing regulations and guidance.
 - i. Intuitive's marketing and sale of EndoWrist instruments with usage limits is consistent with FDA's regulatory requirements.
 - ii. Intuitive's cybersecurity measures are consistent with FDA expectations for devices that are vulnerable to cybersecurity threats.
 - iii. Intuitive's internal conduct does not contradict applicable FDA regulations and guidance, nor does it negate the duty of third-party companies to comply with existing FDA regulations and guidance.

III. Medical Device Regulatory Overview

A. FDA Regulatory Authority

1. Statutory Authority

17. The Food and Drug Administration (FDA) is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices, and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.¹

18. FDA is responsible for advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by

¹ FDA Mission Statement, available at <https://www.fda.gov/about-fda/what-we-do> (last accessed Jan. 17, 2023).

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health.²

19. The mission of FDA is to enforce laws enacted by Congress and regulations established by the Agency to protect the consumer's health, safety, and pocketbook. Its primary focus is the enforcement of the Federal Food, Drug, and Cosmetic Act (the "FD&C Act" or "Act"), the basic food and drug law of the U.S. The law is intended to, in part, assure, that drugs and devices are safe and effective for their intended uses and that all labeling and packaging is truthful, informative, and not deceptive.³

20. As such, the FDA is the federal entity responsible for providing regulatory oversight of the manufacturing, sale, and distribution of medical devices in the United States. FDA's authority comes from the Act, as amended by the Medical Device Amendments of 1976 and subsequent amendments. The Center for Devices and Radiological Health (CDRH), a Center located within the FDA, has primary responsibility for implementing these authorities.

2. Regulation

21. The scope of FDA's regulatory authority is very broad, and its responsibilities are closely related to those of several other government agencies.⁴ Federal regulations are either required or authorized by statute.

² Ibid.

³ FDA, FDA Related Laws, Regulations, and Guidances, <https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/fda-related-laws-regulations-and-guidances> (last accessed Jan. 17, 2023); FDA, Federal Food, Drug, and Cosmetic Act (FD&C Act), <https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act> (last accessed Jan. 17, 2023).

⁴ FDA, Regulatory Information, <https://www.fda.gov/regulatory-information> (last accessed Jan. 17, 2023).

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

22. FDA enacts regulations that interpret the FD&C Act and related statutes.

FDA regulations are collected in the Code of Federal Regulations (CFR), Section 21, and published in the Federal Register, as required by law.

3. [Guidance Documents](#)

23. FDA's regulatory authority begins with the law or statute that is passed by Congress, which is then refined and expanded upon in regulation. FDA also issues "guidance documents," which are intended to provide FDA's current thinking on a topic.

24. In 1997, FDA published its policy on "Good Guidance Practices" (GGP's), which sets forth the agency's policies and procedures for the development, issuance, and use of guidance documents.⁵ As to the legal effect of guidance documents, the policy noted that while guidance does not bind the agency or the industry:

[T]hey explain how the agency believes the statutes and regulations apply to certain regulated activities. However, because a guidance document represents the agency's current thinking on the subject addressed in the document, FDA's decision makers will take steps to ensure that their staff do not deviate from the guidance document without appropriate justification and appropriate supervisory concurrence.⁶

25. The policy provided some standard language that is included at the beginning of all subsequently issued FDA guidance:

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and

⁵ 62 Fed. Reg. 8961 (Feb. 27, 1997).

⁶ Ibid. at 8963.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

*regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.*⁷

26. In 2000, this policy was formalized into regulation.⁸

27. Guidance documents are a critical part of the premarket review program, including the 510(k) program. Example of the types of guidance documents that FDA issues include:

- program specific guidance documents, such as the 510(k) Program which described how to evaluate substantial equivalence,⁹ the 510(k) Format which discusses the format and content for 510(k) submissions,¹⁰ and the Modifications guidance document which describes when modifications require the need for a new 510(k) submission¹¹ as well as a specific modifications guidance for software changes;¹²

⁷ For example, this language appears in the FDA guidance document, “Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications)” (Aug. 30, 2019) (originally issued Mar. 28, 2012), available at <https://www.fda.gov/media/99769/download> (last accessed Jan. 17, 2023).

⁸ 21 CFR § 10.115.

⁹ FDA, “The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]” (July 28, 2014), available at <https://www.fda.gov/media/82395/download> (last accessed Jan. 17, 2023).

¹⁰ FDA, “Format for Traditional and Abbreviated 510(k)s” (Sept. 13, 2019) (originally issued Aug. 12, 2005), available at <https://www.fda.gov/media/130647/download> (last accessed Jan. 17, 2023).

¹¹ FDA, “Deciding When to Submit a 510(k) for a Change to an Existing Device” (Oct. 25, 2017) (originally issued Jan. 10, 1997), available at <https://www.fda.gov/media/99812/download> (last accessed Jan. 17, 2023).

¹² FDA, “Deciding When to Submit a 510(k) for a Software Change to an Existing Device” (Oct. 25, 2017), available at <https://www.fda.gov/media/99785/download> (last accessed Jan. 17, 2023).

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

- device specific guidance documents, such as the guidance for Intravascular Filters.¹³; and
- cross-cutting guidance documents. The 510(k) Format guidance recommends that a 510(k) submission contain standardized sections on the following topics: Labeling, Sterilization and Shelf Life, Biocompatibility, Software, and Electromagnetic Compatibility and Electrical Safety. These sections have one or more cross-cutting guidance documents associated with it that apply equally to 510(k)s as well as PMAs.

28. While adherence to the recommendations in guidance documents is not strictly required, in practice FDA expects manufacturers to follow them closely or to have a very good justification or rationale for not following the identified recommendations.¹⁴

B. Medical Device Classification

29. FDA, by law, uses a risk-based classification scheme for products that meet the legal definition of a medical device.

30. The Act defines a device¹⁵ as:

an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

¹³ Due to the large number of device types, FDA has not issued device specific guidance documents for the majority of device types.

¹⁴ Similarly, while draft guidance documents do not have the force of final guidance documents, draft guidance documents are instructive and, when finalized, would represent FDA's current thinking on a topic.

¹⁵ FD&C Act, 21 U.S.C. § 321(h)(1).

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

(C) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

31. The Act establishes three classes of medical devices based on the risk of the device and provides for regulatory controls that are commensurate with the risk and the ability to control that risk.¹⁶

32. Class I devices are the lowest risk devices, for which “general controls” are adequate to provide a reasonable assurance of safety and effectiveness.¹⁷

33. General controls include a prohibition against adulteration or misbranding, registration of device manufacturing facilities, listing of the device types, records and reports (including adverse event reports, device tracking, if ordered, unique device identification and reports of corrections or removals), repair, replacement and refund, as well as provisions regarding banned devices and compliance with good manufacturing practices (unless exempt by regulation). Most Class I devices are exempt from any premarket notification requirements.¹⁸

34. Examples of Class I devices include canes, crutches, patient exam gloves, bandages and scalpels.

¹⁶ 21 U.S.C. § 360c(a).

¹⁷ 21 U.S.C. § 360c(a)(1)(A).

¹⁸ FDA, Regulatory Controls, <https://www.fda.gov/medical-devices/overview-device-regulation/regulatory-controls> (last accessed Jan. 17, 2023).

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

35. Class II devices are moderate risk devices, for which there is sufficient information to establish special controls to provide a reasonable assurance of safety and effectiveness. These devices cannot be classified into Class I because general controls by themselves are insufficient to provide such an assurance.¹⁹

36. Special controls can include performance standards, postmarket surveillance, patient registries, special labeling requirements, premarket data requirements and guidelines.²⁰

37. Class II devices are generally subject to FDA review and clearance through the submission of a “premarket notification,” also known as a 510(k).²¹ The 510(k) notification for a Class II device must demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent in terms of intended use and technological characteristics to another Class II (moderate risk) device and comply with any special controls, if promulgated. This process is sufficient, in the FDA’s view, to provide a reasonable assurance of safety and effectiveness for that device type.²² Therefore, each substantially equivalent decision, while not an independent determination of reasonable assurance of safety and effectiveness like that which is required for a premarket approval for a Class III device (discussed below), can still be considered a determination of reasonable assurance of safety and effectiveness because it

¹⁹ 21 U.S.C. § 360c(a)(1)(B).

²⁰ FDA, Regulatory Controls, <https://www.fda.gov/medical-devices/overview-device-regulation/regulatory-controls> (last accessed Jan. 17, 2023).

²¹ 21 U.S.C. § 360c(a)(1)(B).

²² FDA, Premarket Notification 510(k), <https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k> (last accessed Jan. 17, 2023).

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

leverages the body of knowledge that allowed for the device to be classified as Class II. The 510(k) notification is discussed in more detail in Section III.C.

38. Examples of Class II devices include ventilators, hip implants with metal/polymer bearing surfaces, soft contact lenses, X-ray equipment, MRI devices, infusion pumps, biopsy devices, and surgical instruments for use with specific devices such as surgical mesh for stress urinary incontinence.

39. Class III devices are the highest risk or most novel device types, for which general and special controls are not adequate to provide a reasonable assurance of safety and effectiveness.²³

40. Because they present the highest risk, they are generally subject to FDA review and approval of a premarket approval application, commonly referred to as a PMA, which requires an independent demonstration of a reasonable assurance of safety and effectiveness, based on valid scientific evidence.²⁴

41. Examples of Class III devices include implantable defibrillators, drug-eluting coronary stents, implantable diaphragmatic/phrenic nerve stimulators, and mechanical heart valves.

42. FDA, with the assistance of Congressionally mandated medical advisory panels, has established classifications for approximately 1,700 different generic types of devices and grouped them into 16 medical specialties referred to as panels.²⁵ Each of these generic

²³ 21 U.S.C. § 360c(1)(C).

²⁴ Ibid.

²⁵ FDA, Classify Your Medical Device, <https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device> (last accessed Jan. 17, 2023).

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

types of devices is assigned to one of the three regulatory classes based on the level of control necessary to reasonably assure the safety and effectiveness of the device. Information about the device types that have been classified can be found in 21 Code of Federal Regulations (CFR) §§ 862 – 892, or by searching FDA's classification database.²⁶

43. In addition to the classifications in the Act and the regulations, FDA also identifies device types using product codes (also known as "procodes"). FDA assigns a unique 3-letter product code for each generic type of device, whether it has been formally classified by FDA or not. One classification regulation may include multiple procodes.²⁷

44. For all classes, FDA's standard is the same: there must be "reasonable assurance" that the device is safe and effective. For class I devices, general controls alone provide a reasonable assurance of safety and effectiveness; for Class II devices, general plus special controls provide a reasonable assurance of safety and effectiveness; for class III devices, premarket approval provides a reasonable assurance of safety and effectiveness. While 510(k) clearance is a less rigorous process than premarket approval, that is because it only applies to device types that the FDA and its medical panels have found to present moderate risks.

45. It is important to note that FDA is responsible for assigning the appropriate regulatory classification and regulatory submission type. FDA selects an appropriate pathway after the agency reviews the relevant known risks and benefits and determines if those known risks can be adequately controlled by regulatory tools such as

²⁶ <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/PCDSimpleSearch.cfm>

²⁷ FDA, "Medical Device Classification Product Codes" (Apr. 11, 2013), available at <https://www.fda.gov/media/82781/download> (last accessed Jan. 17, 2023).

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

general and special controls. Based on that review, FDA then establishes the regulatory classification, which determines the required regulatory pathway that manufacturers must follow.

46. The use of the 510(k) pathway as dictated by FDA is not a “bypass” of the premarket approval process nor is it a temporary status. It is what FDA requires for device types that present a moderate risk.

47. You would not have a circumstance where a high-risk device has been placed into Class III by FDA and requires the submission of a PMA, yet a manufacturer would opt to submit a 510(k) rather than a PMA, or vice versa.

48. FDA decides whether the manufacturer must use 510(k) clearance or must instead seek premarket approval. The manufacturer does not get to choose the application pathway that it prefers but must adhere to the regulatory pathways that FDA establishes for each device type.

C. Premarket (510(k)) Notification

49. A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device. Each person who wants to market in the U.S., a Class I, II, and III device intended for human use, for which a Premarket Approval application (PMA) is not required, must submit a 510(k) to FDA unless the device is exempt from 510(k) requirements of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and does not exceed the limitations of exemptions in .9 of the device classification regulation chapters (e.g., 21 CFR 862.9, 21 CFR 864.9). Before marketing a device, each submitter must receive an order, in the form of a letter,

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

from FDA which finds the device to be substantially equivalent (SE) and states that the device can be marketed in the U.S. This order "clears" the device for commercial distribution.

1. [Background on 510\(k\) Notification](#)

50. As discussed in Section III.B., certain devices (Class II) are subject to the premarket (510(k)) notification requirement.

51. Devices that are subject to the premarket notification requirement cannot be legally marketed in the United States until FDA has issued an order finding that the device is "substantially equivalent (SE)" to a "predicate" device.

52. Under the FD&C Act, "each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use shall, at least ninety days before making such introduction or delivery, report to the Secretary . . . (in such form and manner as the Secretary shall by regulation prescribe)—

(1) the class in which the device is classified under section 360c of this title or if such person determines that the device is not classified under such section, a statement of that determination and the basis for such person's determination that the device is or is not so classified, and

(2) action taken by such person to comply with requirements under section 360d or 360e of this title which are applicable to the device."²⁸

53. A predicate device is a legally marketed device to which a new device may be compared for a determination regarding substantial equivalence. It could be a device

²⁸ 21 U.S.C. § 360(k).

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

that was legally marketed prior to May 28, 1976, or a device which has been reclassified from Class III to Class II or Class I, or a device which has been found to be substantially equivalent through the 510(k) premarket notification process.²⁹

54. A premarket notification submission is also required when a manufacturer makes significant changes or modifications to a device that it has already introduced or plans to reintroduce into commercial distribution.³⁰

55. 21 CFR 807.81(a)(3) states that a premarket notification 510(k) submission is required when the device “is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, that is about to be significantly changed or modified in design, components, method of manufacture, or intended use. A significant change or modification requiring a premarket notification includes “a change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process.”³¹

56. FDA notes in the 510(k) Modifications guidance: “To determine whether a change or modification could significantly affect the safety or effectiveness of a device, the manufacturer should first conduct a risk-based assessment, using the guidance below, of whether the change could significantly affect the device’s safety or effectiveness, either positively or negatively. This risk-based assessment should identify and analyze all new risks

²⁹ 21 CFR § 807.92(a)(3).

³⁰ 21 CFR § 807.81(a)(3).

³¹ 21 CFR § 807.81(a)(3)(i).

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

and changes in existing risks resulting from the device change, and lead to an initial decision whether or not submission of a new 510(k) is required.”³²

2. Substantial Equivalence

57. FDA has issued regulations³³ and guidance³⁴ specifying the contents of a 510(k) notification. The 510(k) submission is not a form, but a compilation of specific information regarding a medical device to demonstrate the equivalence of the new device to a predicate device. In brief, the submitter must provide a description of the device, a comparison to the predicate device(s), and data that demonstrate that the device is substantially equivalent. The data can include bench testing as well as animal or clinical data.

58. For FDA to determine that a new device is substantially equivalent to a predicate device, FDA must determine that the device:

(i) has the same technological characteristics as the predicate device, or

(ii)(I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary by the Secretary that demonstrates that the device is as safe and effective as a legally marketed device, **AND**

³² FDA, “Deciding When to Submit a 510(k) for a Change to an Existing Device,” at 8.

³³ 21 CFR § 807.87.

³⁴ FDA, “Format for Traditional and Abbreviated 510(k)s” (Sept. 13, 2019) (originally issued Aug. 12, 2005), available at <https://www.fda.gov/media/130647/download> (last accessed Jan. 17, 2023).

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

(II) does not raise different questions of safety and effectiveness than the predicate device.³⁵

59. The term “different technological characteristics” means, with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device.³⁶

60. The same definitions of safety and effectiveness apply to all devices, regardless of class:

*There is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks.*³⁷

...

*There is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.*³⁸

61. As explained earlier, for both safety and effectiveness, the regulatory standard is “reasonable assurance.” At the time of the initial Medical Device Amendments, it

³⁵ 21 U.S.C. § 360c(i)(1)(A) (emphasis added).

³⁶ 21 U.S.C. § 360c (i)(1)(B).

³⁷ 21 CFR § 860.7(d)(1).

³⁸ 21 CFR § 860.7(e)(1).

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

was noted that this standard is “*predicated upon the recognition that no regulatory mechanisms can guarantee that a product will never cause injury, or will always produce effective results. Rather, the objective of the legislation is to establish a mechanism in which the public is afforded reasonable assurance that medical devices are safe and effective.*”³⁹

62. FDA issued a final guidance entitled “*The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] Guidance for Industry and Food and Drug Administration Staff*” on July 28, 2014.⁴⁰ This guidance superseded FDA’s longstanding “*Guidance on the CDRH Premarket Notification Review Program, 510(k) Memorandum K86-3,*” dated June 30, 1986. Both guidance documents provided guidance on how to determine if a medical device is substantially equivalent. The same logic and questions apply in both guidance documents. A main difference in the newer guidance is that it provides greater clarity on the appropriate use of multiple predicates by including the concept of a reference device. This difference between the two guidance documents has no bearing on this case. A flowchart was also included to serve as an aid in making the SE determination.

63. If FDA determines that a new device is substantially equivalent to a predicate device, it will issue a letter known as a “Substantially Equivalent” or “SE” Letter allowing the device to be marketed. The device is then said to be “cleared.”⁴¹

³⁹ H.R. Rept. 94-853, at 15 (Feb. 29, 1976).

⁴⁰ Available at <https://www.fda.gov/media/82395/download> (last accessed Jan. 17, 2023).

⁴¹ There is a regulatory distinction between “clearance” and “approval”, but people commonly confuse the two terms because “clearance” today requires that FDA grant permission to market the device. It is not uncommon to see references to devices cleared through the 510(k) process as being “FDA Approved.” 21 CFR § 807.97 indicates that any representation that creates an impression of official approval of a device because of complying with the premarket

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

64. FDA will post the clearance and provide a copy of the "SE Letter," "Indications for Use Form" and "510(k) Summary" (if available) on the FDA website.⁴²

3. Deficiency Letters

65. During the course of a review, when FDA has questions or concerns about an application, it can ask for additional information. This is done typically in one of two ways. FDA can ask interactive questions by email where the FDA review clock is not stopped and the sponsor has a short time to respond or FDA can send a deficiency letter that places the submission on hold and the sponsor has a longer timeframe to respond. FDA typically issues only one deficiency letter during the review process, however, certain circumstances may allow for the issuance of a second letter.

66. In a deficiency letter, FDA will distinguish between major deficiencies, which, if not adequately resolved, may preclude a favorable decision on the marketing application, and minor deficiencies, which can be resolved in a straightforward manner but need to be addressed to meet regulatory requirements or to prevent potential misbranding or adulteration.

IV. Opinions and Bases for Opinions

67. In formulating my opinions, which apply the appropriate regulatory framework as discussed above, I have reviewed publicly available information as well as the documents produced through discovery. I conducted a thorough review of relevant information

notifications regulations is misleading and constitutes misbranding. However, FDA currently does not routinely enforce this regulation absent other violations.

⁴² Available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm>.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

necessary to develop my opinions regarding the activities at issue. The methods that I used are similar to the methods that I have employed throughout my career, including those methods that I used as a reviewer, manager and senior manager at the Food and Drug Administration and as a consultant to medical device companies.

- A. Opinion 1 – Remanufacturing medical devices is a manufacturing activity, which is subject to FDA regulatory requirements, including premarket notification, registration, recall, medical device reporting, unique device identification, and postmarket surveillance among others.

68. Remanufacturing is clearly defined by FDA in existing regulations.

69. Plaintiff and the relevant third parties in this case have suggested that the definition of “remanufacturing” is a “murky area” because FDA has not published final guidance on all distinctions between remanufacturing and servicing.⁴³ But FDA’s definition of remanufacturing has been clear since the promulgation of 21 CFR 820 in 1996,⁴⁴ and there is no doubt that a party that engages in the activities described in the regulation is a remanufacturer.

70. 21 CFR Part 820 (the Quality System Regulation) (the “QSR”) provides the FDA regulatory requirements for good manufacturing practices for medical devices. FDA explained: “The provisions of this part shall be applicable to any finished device as defined in this part, intended for human use, that is manufactured, imported, or offered for import in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.”⁴⁵

⁴³ Intuitive-00706083, at -6086.

⁴⁴ 61 Fed Reg. 52602 (Oct. 7, 1996).

⁴⁵ 21 CFR § 820.1(a)(2).

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

71. The QSR defines both “manufacturer” and “remanufacturer”:

(o) A manufacturer is any person who designs, manufactures, fabricates, assembles, or processes a finished device.

Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions.

...

(w) A remanufacturer is any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.⁴⁶

72. When FDA proposed its revisions to 21 CFR 820,⁴⁷ it solicited comments on the definitions published in the proposed rule. The preamble to the final rule (Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation⁴⁸), specifically the Agency’s Response 28, discusses those comments as well as the Agency response to those comments:

Several comments in response to the proposed definition of “manufacturer” stated that refurbishers and servicers should be added to the definition of a “manufacturer.” Other comments recommended adding the term “remanufacturer.” Other comments requested deletion of contract sterilizers, installers,

⁴⁶ 21 CFR § 820.3.

⁴⁷ Under Section 520(f) of the Act, FDA issued a final rule in the Federal Register of July 21, 1978 (43 FR 31 508), prescribing Current Good Manufacturing Practice (CGMP) requirements for the methods used in, and the facilities and controls used for the manufacture, packing, storage, and installation of medical devices. This regulation became effective on December 18, 1978, and is codified under 21 CFR part 820. In November 1993, the agency issued its proposed revisions to the regulation. 58 Fed. Reg. 61952 (Nov. 23, 1993).

⁴⁸ 61 Fed. Reg. 52602 (Oct. 7, 1996).

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

specification developers, repackagers, relabelers, and initial distributors from the definition.

One comment stated that the phrase “processes a finished device” should be explained in the definition of manufacturer.

FDA’s Compliance Policy Guide (CPG) 7124.28 contains the agency’s policy regarding the provisions of the act and regulations with which persons who recondition or rebuild used devices are expected to comply. This CPG is in the process of being revised in light of FDA’s experience in this area. . . . Because of a number of competitive and other issues, including sharply divided views by members of the GMP Advisory Committee at the September 1995 meeting, FDA has elected to address application of the CGMP requirements to persons who perform servicing and refurbishing functions outside the control of the original manufacturer in a separate rulemaking later this year, with another opportunity for public comment.

FDA agrees that the term “remanufacturing” should be added to the definition of “manufacturer” and has separately defined the term. A remanufacturer is defined as “any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device’s performance or safety specifications, or intended use.”⁴⁹

73. This discussion in the preamble signifies that thought was specifically given to the inclusion of remanufacturing as part of the definition of “manufacturer,” including developing a separate definition for the new term “remanufacturer,” and that this was supported by comments that were received on the proposed rule.

⁴⁹ 61 Fed. Reg. 52602 at 52609 (Oct. 7, 1996). FDA solicited public comments on the proposed rule until October 23, 1995. Approximately 280 separate individuals or groups commented on the proposal published in the Federal Register of November 23, 1993, and approximately 175 separate individuals or groups commented on the Working Draft that was announced in a notice of availability published in the Federal Register on July 24, 1995.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

74. Phillips suggests that the supposed “lack of clarity” related to FDA’s definition of “refurbishing” or “servicing” is of import in this case.⁵⁰ However, where a party engages in the activities listed in the definition of “remanufacturer,” there can be no doubt that the party is a remanufacturer and is subject to the associated regulatory requirements.

B. Opinion 2 – EndoWrist instruments were cleared by FDA as limited use devices, and efforts to remove or extend the usage limitation by companies other than the original equipment manufacturer (OEM) constitute remanufacturing activities.⁵¹

1. FDA cleared EndoWrist instruments as limited use devices.

75. The usage limitation is an essential safety and performance specification for the EndoWrist instruments. Intuitive engaged in extensive life and performance testing, which was submitted to FDA, to provide FDA a reasonable assurance of the safety and the effectiveness of the device.

76. The device descriptions in both K965001 and K990144, the earliest 510(k) submissions for the da Vinci Surgical System and its instruments, state that the instruments are “resposable” and “limited use.”⁵² The fact that the “indications for use” in the 510(k) summaries do not specifically state that EndoWrist instruments are subject to limited use makes no difference, as the usage limitations were clearly indicated in the device descriptions and elsewhere in the 510(k) submission.

⁵⁰ Opening Expert Report of Philip J. Phillips (Dec. 2, 2022) (“Phillips Report”) § III.F, ¶ 114.

⁵¹ Efforts to remove or extend the usage limitation by the OEM, Intuitive, constitute manufacturing and are also subject to premarket requirements.

⁵² Intuitive-00691660; Intuitive-00692314.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

77. In order to understand FDA's clearance of EndoWrist instruments as limited use devices, it is helpful to look at certain premarket submissions for EndoWrist instruments.

a) [K990144](#)

78. The original 510(k) for Intuitive's EndoWrist family of instruments as well as subsequent 510(k)s demonstrate that the instruments were cleared by FDA as limited use devices.

79. On January 18, 1999, Intuitive submitted a 510(k) for additional instruments to be used with the Intuitive Surgical Endoscopic Instrument Control System (Model IS1000), including scissors, scalpels, forceps, clip applier, electrocautery and accessories, pick-ups and needle drivers/holder.⁵³ The trade name listed for the instruments in this 510(k) was Intuitive Surgical™ Instruments/Accessories: "Resposable" (limited reuse) Endoscopic Instruments.

80. In its Substantial Equivalence Comparison/Rationale, Intuitive explained: "Intuitive Surgical has worked hard to reduce risks associated with the use of the Endoscopic Instrument Control System to an absolute minimum. This has been done through extensive failure modes effects and criticality analysis (FMECA) . . . and extensive fail-safe and redundant design assuring no uncontrolled instrument movement. This fail-safe design has been verified and validated through both in vitro and in vivo testing including more than 170 clinical procedures to date."⁵⁴

⁵³ Intuitive-00692310.

⁵⁴ Intuitive-00692321, at -2324-25.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

81. Intuitive provided the instrument and accessory physical specifications to FDA, and explained that “Tool ID electronics . . . provide electronic recognition of the tool, and store number of uses remaining in memory.”⁵⁵

82. Furthermore, “[t]he system electronics is responsible for performing all telepresence control functions and video processing functions of a sophisticated electro-mechanical system in a surgical environment. Additionally, and of at least equal importance, it is responsible for detecting system faults and taking such protective actions as necessary so as to ensure both patient and operating room staff safety under all conceivable failure conditions.”⁵⁶

83. FDA solicited additional information from Intuitive on the limited use nature of its instruments as part of the 510(k) review. Among FDA’s requests was a “summary of your validation of the reuse instructions for the ‘resposables’” and “a mechanism for assuring that single use instruments such as scalpels and electrocautery will not be confused with ‘resposable’ and will not be reused.”⁵⁷

84. Intuitive explained in Section 3.8 of the Device Description, “Summary of Pre-Clinical Studies,” the testing done to ensure mechanical reliability. Intuitive explained, “*In vitro* component and sub-system cycle life and durability testing has been performed. This work has included mechanical arms and instruments and has demonstrated reliability consistent with product labeling and use recommendations. Instruments are programmed to “expire” and not

⁵⁵ Intuitive-00692451, at -2454.

⁵⁶ Intuitive-00692433, at -2436.

⁵⁷ Intuitive-00692185, at -2205-06.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

be useable after a predetermined amount of usage in order to assure reliable operation and the absence of “wear out.”⁵⁸

85. On July 11, 2000, FDA cleared the instruments, writing, “Based upon the product technical information, intended use, and performance information provided in the pre-market notification, the Intuitive Surgical Endoscopic Instrument Control System has been shown to be substantially equivalent to currently marketed predicate devices.”⁵⁹

b) [K013416](#)

86. On October 12, 2001, Intuitive submitted another 510(k) for certain EndoWrist instruments, including endoscopic forceps, graspers, needle drivers, scissors, scalpels (K013416). In the 510(k) Summary, Intuitive explained: “The subject device(s) consist of a family of endoscopic instruments with either grasping or cutting and effectors to be used with the Intuitive Surgical da Vinci Endoscopic Instrument Control System. . . . The instruments are re-usable (for a limited number of uses), are provided non-sterile, and must be cleaned and sterilized before use (pre-vacuum autoclave). . . . The instruments are provided for a limited number of uses to ensure reliability and consistent performance, and have non-volatile ‘add-only’ memory that the Instrument Control System decrements after each use.”⁶⁰

87. Intuitive also provided testing data in this submission. It explained that standard bench testing data was performed for each of the subject EndoWrists as part of

⁵⁸ Intuitive-00692611, at -2634.

⁵⁹ Intuitive-00691203, at -1204.

⁶⁰ Intuitive-00515501, at -5508-09.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

standard verification and validation testing conducted prior to commercial introduction.⁶¹ The testing included a life cycle test: “Perform range of motion cycles on each wrist axis based on expected range of motion during surgical procedures to determine that the cables don’t derail or fray, that the pulley turns, and that the wrist unit functions correctly after the test.”⁶² Intuitive also noted that there were no FDA performance standards for these devices, but the EndoWrists were “designed, manufactured, and tested in accordance with voluntary safety standards.”⁶³

88. On December 12, 2001, the FDA sent a deficiency letter to Intuitive regarding the K013416 filing, requesting that Intuitive address the identified deficiencies related to usage limits, biocompatibility, and Ultrasonic Shears.⁶⁴ Specifically, the FDA wrote, “On page 12, you state that the instruments are re-usable for a limited number of uses. The instruments are programmed for a limited number of uses to ensure reliability and consistent performance, and have non volatile ‘add-only’ memory that the system decrements after each use. Please specify the number of uses for each instrument and describe how the numbers were determined. Please provide data to support the claim.”⁶⁵

89. Intuitive explained to FDA that the “number of uses is determined by testing instruments under conditions that replicate actual clinical use, and cycling these

⁶¹ Ibid. at -5519.

⁶² Ibid. at -5521.

⁶³ Ibid. at -5527.

⁶⁴ Intuitive-00481165.

⁶⁵ Ibid. at -1166.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

instruments for wear expected during the specified number of procedures. . . . Performance measurements are made periodically (e.g., at the end of each cycle or set of cycles) to confirm that the instrument is still performing as intended, and the life testing is continued until failure or a specified number of cycles are successfully completed.”⁶⁶

90. On January 10, 2002, FDA granted clearance for the K013416 510(k).⁶⁷

c) [K131861](#)

91. On June 19, 2013, Intuitive submitted a 510(k) for its Model IS4000 Da Vinci Xi surgical system and EndoWrist instruments (K131861).

92. As with the earlier submissions, Intuitive submitted performance testing data, including life testing data, demonstrating that the EndoWrist instruments had been validated for a certain number of uses.⁶⁸

93. On March 28, 2014, FDA granted clearance for the K131861 510(k) submission.⁶⁹

d) [K170644](#)

94. This 510(k) applies to multiple instruments and accessories that have been cleared through a number of 510(k) Premarket Notifications, including the 8mm Si Monopolar Curved Scissors. It concerns the Reprocessing Instructions provided to users for reprocessing of instruments and accessories intended for multiple usage.

⁶⁶ Ibid. at -1168.

⁶⁷ Intuitive-00481176.

⁶⁸ Intuitive-00493612.

⁶⁹ Intuitive-00861667.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

95. This device was also listed as a predicate device for the K210478 510(k), discussed below in Section IV.B.1(h), in which Iconocare sought clearance for an additional 10 uses beyond what was originally cleared by FDA for the 8mm Si Monopolar Curved Scissors.

96. This submission validated the devices for the labeled number of reprocessing cycles for the instruments establishing that the device meets performance specifications after a representative number of uses.

e) [K180033](#)

97. This 510(k) was submitted by Intuitive Surgical for the EndoWrist 8mm Monopolar Curved Scissors instrument used with the Intuitive Surgical IS2000 da Vinci S Surgical System or IS3000 da Vinci Si Surgical System for cutting, cauterizing, coagulation, manipulating and blunt dissection of tissue.

98. This device was listed as one of the predicate devices for K210478. Specifically, Iconocare submitted the K210478 510(k) to seek clearance for an additional 10 uses beyond what was cleared in this 510(k) for the Si 8mm Monopolar Curved Scissors.

f) [K214095](#)

99. In December 2021, Intuitive submitted a 510(k) to FDA for “extended lives” on certain instruments intended for use with the X and Xi da Vinci Surgical Systems.⁷⁰

⁷⁰ Intuitive-02054168.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

100. The submission included testing data demonstrating that the X/Xi EndoWrist instruments could be used for a greater number of lives than the number for which they were originally cleared.⁷¹

101. On August 15, 2022 FDA notified Intuitive that clearance was granted for K214095.⁷²

g) [K143619](#)

102. I am aware of two manufacturers other than Intuitive who have submitted 510(k)s seeking clearance to extend the usage limits on EndoWrist instruments: Rebotix, LLC and Iconocare Health.

103. Rebotix submitted K143619 on December 18, 2014 for “re-manufactured EndoWrists.”⁷³ According to Rebotix:

Re-manufactured EndoWrists are intended to be used in the same manner as their OEM counterparts. The conditions of use and operating principle are identical. The re-manufactured EndoWrists described above can only be used with the da Vinci S and da Vinci Si Systems, in accordance with the indication of these host systems.

Specifications and allowable tolerances have been established for each of the remanufactured EndoWrists, in order to ensure that they maintain OEM-equivalent safety and performance throughout the intended extended use cycles.⁷⁴

⁷¹ K214095 510(k) Summary, available at: https://www.accessdata.fda.gov/cdrh_docs/pdf21/K214095.pdf. This 510(k) is discussed in further detail in Section IV.D.3.

⁷² Ibid.

⁷³ REBOTIX170421, at -0424.

⁷⁴ REBOTIX131433 at -1436.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

104. Following review of the submission and months of communications with Rebotix regarding the submission,⁷⁵ FDA issued a deficiency letter to Rebotix on June 23, 2015 that identified 51 deficiencies with the submission.⁷⁶ The deficiencies related to the device description, remanufacturing, labeling, cleaning validation, sterilization validation, biocompatibility, electromagnetic compatibility and electrical safety, and performance testing.⁷⁷

105. It is worth noting that Phillips suggests that FDA's review of a 510(k) is not an affirmation that the subject of the 510(k) submission is "necessary."⁷⁸ However, in my experience, FDA does not devote the necessary resources to identify and describe deficiencies at this level of detail where FDA considers the 510(k) "unnecessary."

106. The term "remanufacture" (or a version of it) was used 84 times in the deficiency letter. The letter includes a specific section of deficiencies under the heading "Remanufacturing." It states:

Remanufacturing

The following deficiencies refer to the procedures you have identified to collect used devices from users, and modify those devices to accommodate additional uses (defined as "remanufacturing" for the purpose of this letter).

2. Although the subject device is not a "single-use device" (defined as a device used only once and then discarded), it has

⁷⁵ See, e.g., REBOTIX131417; REBOTIX077440; REBOTIX077545; REBOTIX077617; REBOTIX077671.

⁷⁶ REBOTIX171030.

⁷⁷ Ibid. at -1030-57.

⁷⁸ Phillips Report, ¶ 37.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

many aspects in common with third party reprocessed single-use devices. Therefore, it is recommended that you review and provide the following items described in FDA's Guidance "Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices"⁷⁹ . . .

107. It is clear from the content of the 510(k) and from FDA's deficiency letter that both Rebotix and FDA considered the activities described in this submission, which would extend the use of the EndoWrist devices for an additional 11 uses over the original clearance, to be remanufacturing.

108. FDA never cleared Rebotix's "re-manufactured EndoWrists." In the deficiency letter, FDA made clear: "You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act."⁸⁰ Again, the Phillips report tries to downplay this language by describing it as "boilerplate." In my opinion, whether it is "boilerplate" or not, FDA expects a company intending to market a new device to abide by the regulatory requirements, and would not tell a company that marketing a device would be a violation of the FD&C Act if FDA did not believe that to be the case.⁸¹

⁷⁹ REBOTIX171030; The guidance FDA recommended is available at <https://www.fda.gov/media/71482/download> (last accessed Jan. 17, 2023).

⁸⁰ REBOTIX171058.

⁸¹ FDA may apply enforcement discretion in cases where a company made a good faith determination that a 510(k) was not needed and is actively working towards bring a product into compliance. The language in the letter indicates to me that FDA was not applying enforcement discretion here.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

109. Rebotix attempted to cure the deficiencies in its submission and engaged with FDA on various calls and e-mails to gain clarity on the required activities Rebotix would need to undertake.⁸² FDA explained to Rebotix that certain deficiencies stemmed “from the fact that the device is not simply a reusable device, but is a third party reprocessed/remanufactured device.”⁸³

110. Ultimately, Rebotix notified FDA of its intent to “formally withdraw the K143619 submission” and withdrew the submission on December 17, 2015, citing “the nature of the testing and information requested.”⁸⁴ Rebotix indicated that it intended to resubmit the 510(k) at a later date, but I have seen no evidence that they did.

h) [K210478](#)

111. K210478 is the other non-OEM 510(k) submission I am aware of that seeks to extend the useful life of EndoWrist instruments.

112. It too illustrates the applicable regulatory requirements. This 510(k) was submitted by Iconocare Health in February 2021, specifically seeking clearance to add 10 uses to another manufacturer’s legally marketed device.

(1) [Background](#)

113. This 510(k) is for the 8mm Monopolar Curved Scissors Instrument used with the Intuitive Surgical IS3000 da Vinci Si Surgical System for cutting, cauterizing, coagulation, manipulating and blunt dissection of tissue. The instrument consists of the

⁸² REBOTIX077729; REBOTIX077735.

⁸³ REBOTIX077729, at -7733.

⁸⁴ REBOTIX171076.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

housing, shaft, wrist, and tip. The shaft and wrist allow for different axes of rotation, and the instrument tip is used to interact with the patient tissue. This instrument is reusable and is provided non-sterile.⁸⁵

114. The 8mm Monopolar Curved Scissor Instruments are designed by Intuitive to provide surgeons with natural dexterity and a greater range of motion than even the human hand. This allows for greater precision when operating in a minimally invasive environment. EndoWrist 8mm Monopolar Curved Scissor Instruments, when used with the IS3000 system, are designed to support rapid and precise suturing, dissection and tissue manipulation in surgical procedures.⁸⁶

115. In the Summary of Technological Characteristics section, which is drafted by submitter, Iconocare explained that the design, materials, and intended use of the 8mm Monopolar Curved Scissor Instruments, after an additional ten (10) reuse cycles, are equivalent to the predicate device. It submitted to FDA that the mechanism of action of the subject device is identical to the predicate device in that the same standard mechanical design, materials, and sizes are utilized. Finally, Iconocare explained that the change in device specifications is to extend the useful life of the 8mm Monopolar Curved Scissor Instruments.⁸⁷

116. In accordance with the FD&C Act and the related FDA regulations, Iconocare submitted performance data as part of its 510(k).⁸⁸ Iconocare represented to FDA

⁸⁵ SIS357813, at -7817.

⁸⁶ Ibid.

⁸⁷ Ibid.

⁸⁸ In accordance with 21 CFR 807.92(b), the 510(k) Summary for K210478 discusses the performance data submitted to support substantial equivalence.
https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210478.pdf

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

that it conducted a risk analysis to evaluate the impact of modifications to the predicate device.

This included the following tests:

- Biocompatibility
- Validation of Reprocessing
- Functional Performance Testing
- Electrical Safety Testing.⁸⁹

117. Iconocare had to submit data sufficient to allow FDA to determine whether its remanufactured device is as safe and effective as the predicate and operates as originally intended.

(2) Deficiencies

118. [REDACTED]

[REDACTED].⁹⁰

119. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]:

[REDACTED]

[REDACTED]

[REDACTED].⁹²

⁸⁹ Ibid.

⁹⁰ AHP000527.

⁹¹ Ibid. at -0528-36.

⁹² Ibid. at -0528.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

120. As I explained above in Section IV.B.1(g), in my experience, especially under the current user fee performance goal structure,⁹³ FDA does not devote the resources required to identify and describe deficiencies at this level of significant detail when FDA considers the 510(k) “unnecessary.”

121. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].”⁹⁴

122. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].”⁹⁶

123. [REDACTED]

[REDACTED]

[REDACTED]

⁹³ The performance goal system establishes a target for FDA to reach a final decision on 95% of 510(k) submissions within 90 FDA days.

⁹⁴ AHP000527, at -0528.

⁹⁵ Ibid.

⁹⁶ Ibid.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

[REDACTED]

[REDACTED]⁹⁷

124. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]⁹⁹

125. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]¹⁰¹

⁹⁷ Ibid. at -0534.

⁹⁸ Ibid. at -0528.

⁹⁹ Available at: <https://www.fda.gov/media/80265/download>

¹⁰⁰ AHP000527 at -0531.

¹⁰¹ Ibid.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

126. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] "102

127. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] "103

128. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] 105

¹⁰² Ibid.

¹⁰³ Ibid. at -0534. (emphasis added)

¹⁰⁴ Available at <https://www.fda.gov/media/71482/download> (last accessed Jan. 17, 2023).

¹⁰⁵ AHP000527, at -0534.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

129. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].”

130. Labeling¹⁰⁶ is defined as all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. Additionally, label is defined in Section 201(k) of the FDCA as a display of written, printed, or graphic matter upon the immediate container of any article.¹⁰⁷ General labeling requirements for medical devices have been established in 21 CFR Part 801.

131. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].”¹⁰⁹

¹⁰⁶ 21 U.S.C. §321(m).

¹⁰⁷ 21 U.S.C. §321(k).

¹⁰⁸ AHP000527, at -0536.

¹⁰⁹ FDA, UDI Basics, <https://www.fda.gov/medical-devices/unique-device-identification-system-udi-system/udi-basics> (last accessed Jan. 17, 2023); FDA, “Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended – Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices” (May 1, 2006), available at <https://www.fda.gov/media/71187/download> (last accessed Jan. 17, 2023).

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

132. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].¹¹⁰

133. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].¹¹¹

134. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].¹¹²

135. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].¹¹³

¹¹⁰ 21 CFR § 801.20(a).

¹¹¹ Restore-00086093, at -6100.

¹¹² Ibid. at -6096-6100.

¹¹³ Ibid. at -6107–08. This appears to contradict Kevin May's recent representation that as long as a hospital "continues to own" an EndoWrist instrument, it can send it to Restore, who

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

(3) Clearance

136. [REDACTED] [REDACTED] [REDACTED]

[REDACTED] "115.

137. Upon clearing the device, FDA assigned this instrument the product codes NAY and QSM. See **Figure 1**.

expects to be purchasing the K210478 clearance from Iconocare and remanufacturing EndoWrists according to Iconocare's cleared process, to have the usage limits reset as many times as "we're willing to reset it." May Tr. 17:21-18:25; 137:23-140:4.

¹¹⁴ K210478 510(k) Summary, available at: https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210478.pdf (last accessed Jan. 17, 2023).

¹¹⁵ Restore-00086093 (emphasis added).

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

Figure 1

Device Classification Name	system, surgical, computer controlled instrument, remanufactured
510(k) Number	K210478
Device Name	8mm Monopolar Curved Scissors
Applicant	Iconocare Health 7825 East Redfield Rd. Suite 103 Scottsdale, AZ 85260
Applicant Contact	Rick Ferreira
Correspondent	Iconocare Health 7825 East Redfield Rd. Suite 103 Scottsdale, AZ 85260
Correspondent Contact	Rick Ferreira
Regulation Number	876.1500
Classification Product Code	QSM
Subsequent Product Code	NAY
Date Received	02/19/2021
Decision Date	09/30/2022
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Gastroenterology/Urology
510k Review Panel	General & Plastic Surgery
Statement	Statement
Type	Traditional
Reviewed by Third Party	No
Combination Product	No

138. As discussed further in Section IV.B.3(a), the NAY product code refers to a “System, Surgical, Computer Controlled Instrument.”¹¹⁶ The QSM code, which was created as a result of this initial clearance for a device cleared as a remanufactured NAY instrument—refers to a “System, Surgical, Computer Controlled Instrument, ***Remanufactured***.”¹¹⁷ The physical state of a device with the QSM code is described by FDA:

A surgical instrument for a computer controlled system. The instrument has been ***remanufactured to extend its use life*** as

¹¹⁶ Product Classification, NAY, available at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpCD/classification.cfm?ID=NAY> (last accessed Jan. 17, 2023).

¹¹⁷ Product Classification, QSM, available at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?id=5726> (last accessed Jan. 17, 2023) (emphasis added).

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

compared to what was originally defined by the original equipment manufacturer.”¹¹⁸

2. [FDA has acknowledged the limited use nature of EndoWrist instruments in communications to third parties.](#)

139. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].”¹¹⁹

140. FDA acknowledged in its 2015 deficiency letter to Rebotix that the EndoWrists could only be validated for a certain number of lives (“[P]lease provide all details regarding the device description, remanufacturing process, validated reprocessing instructions for users, and validated number of use lives . . .”).

141. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].¹²¹

¹¹⁸ Ibid. (emphasis added)

¹¹⁹ Restore-00001248, at -1256; REBOTIX146948, at -6954-55.

¹²⁰ REBOTIX171030.

¹²¹ AHP000527, at -0534.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

142. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].¹²⁴

3. Objective and publicly available evidence demonstrates that FDA has determined that removing or extending the usage limitation on EndoWrist instruments is a remanufacturing activity, and as such, it requires 510(k) clearance.

a) FDA has classified remanufactured EndoWrists as Class II devices, assigned them a unique procode, and indicated that they require 510(k) clearance.

143. FDA's classification of EndoWrist instruments as Class II devices and the assignment of two product codes for the devices demonstrates that FDA views extending the usage limitation on EndoWrist instruments as a remanufacturing activity requiring 510(k) clearance.

144. FDA considers EndoWrist instruments to be robotically-assisted surgical (RAS) devices.

145. RAS devices are a type of computer-assisted surgical system. Sometimes referred to as robotic surgery, RAS devices enable the surgeon to use computer and software

¹²² Ibid. at -0528; REBOTIX171030, at -1034.

¹²³ "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (June 9, 2017), at 20.

¹²⁴ Intuitive-00705778, at -5779.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

technology to control and move surgical instruments through one or more tiny incisions in the patient's body (minimally invasive) for a variety of surgical procedures.¹²⁵

146. In FDA's view, the benefits of a RAS device may include its ability to facilitate minimally invasive surgery and assist with complex tasks in confined areas of the body. The device itself is not actually a robot because it cannot perform surgery without direct human control.¹²⁶

147. RAS devices generally have several components, which may include a:

- Console: Where the surgeon sits during surgery. The console is the control center of the device and allows the surgeon to view the surgical field through a three-dimensional endoscope and control movement of the surgical instruments;
- Bedside cart: Includes three or four hinged mechanical arms, camera (endoscope) and surgical instruments that the surgeon controls during surgical procedures;
- Separate cart: Contains supporting hardware and software components, such as an electrosurgical unit (ESU), suction/irrigation pumps, and light source for the endoscope.¹²⁷

148. FDA classifies RAS devices as Class II devices. Manual surgical instruments for general use (non-powered, hand-held devices) are Class I, exempt from 510(k) under 21 CFR 878.4800. In comparison, because of the risk profile, RAS devices are classified by FDA as Class 2

¹²⁵ FDA, Computer-Assisted Surgical Systems, <https://www.fda.gov/medical-devices/surgery-devices/computer-assisted-surgical-systems> (last accessed Jan. 17, 2023).

¹²⁶ Ibid.

¹²⁷ Ibid.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

and require a 510(k) before the device may be marketed.¹²⁸ Specifically, FDA has determined that RAS devices require both general and special controls in order to provide a reasonable assurance of safety effectiveness, while traditional surgical tools require only general controls.

149. FDA has created two product codes under the regulation 21 CFR § 876.1500 for the instruments that are used with robotically-assisted surgical systems.¹²⁹

150. One product code (NAY) is for what FDA would consider original equipment. See **Figure 2**. NAY refers to “System, Surgical, Computer Controlled Instrument,” and devices with this product code are Class 2. Such a device requires 510(k) clearance to be legally marketed. The product code includes the following statement:

If the device is reusable, validated reprocessing instructions and reprocessing validation data for this device type must be included in a 510(k) submission.

¹²⁸ FDA’s classification of traditional and robotic surgical devices in different classes pertains to FDA’s assessment of the risk profile and the controls necessary to provide reasonable assurance of safety and effectiveness.

¹²⁹ A summary of relevant premarket submissions with the NAY and QSM product codes that have been reviewed and cleared by FDA are summarized in Appendix C.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

Figure 2

Device	System, Surgical, Computer Controlled Instrument
Definition	If the device is reusable, validated reprocessing instructions and reprocessing validation data for this device type must be included in a 510(k) submission (82 FR 26807, available at https://www.gpo.gov/fdsys/pkg/FR-2017-06-09/pdf/2017-12007.pdf).
Regulation Medical Specialty	Gastroenterology/Urology
Review Panel	General & Plastic Surgery
Product Code	NAY
Premarket Review	Surgical and Infection Control Devices (OHT4) General Surgery Devices (DHT4A)
Submission Type	510(k)
Regulation Number	876.1500
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Ineligible
Implanted Device?	No
Life-Sustain/Support Device?	No
Recognized Consensus Standard	<ul style="list-style-type: none"> 12-292 IEEE Std 3333.2.1-2015 IEEE Recommended Practice for Three-Dimensional (3D) Medical Modeling
Third Party Review	Not Third Party Eligible

151. The second product code (QSM) was specifically created for remanufactured products. See **Figure 3**. QSM refers to “System, Surgical, Computer Controlled Instrument, Remanufactured,” and devices with this product code are Class 2. Such a device requires 510(k) clearance to be legally marketed. The product code includes the following statement:

The instrument has been remanufactured to extend its use life as compared to what was originally defined by the original equipment manufacturer.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

Figure 3

Device	System, Surgical, Computer Controlled Instrument, Remanufactured
Definition	As intended with the originally cleared instrument.
Physical State	A surgical instrument for a computer controlled system. The instrument has been remanufactured to extend its use life as compared to what was originally defined by the original equipment manufacturer.
Technical Method	Instrument is attached and manipulated from a primary computer controlled system.
Target Area	Where applicable in accordance to the indications for use.
Regulation Medical Specialty	Gastroenterology/Urology
Review Panel	General & Plastic Surgery
Product Code	QSM
Premarket Review	General Surgery Devices (DHT4A) General Surgery Devices (DHT4A)
Submission Type	510(k)
Regulation Number	876.1500
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Ineligible
Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

152. As discussed in Section IV.B.1(h), FDA granted clearance to Iconocare for a remanufactured EndoWrist (8mm Monopolar Curved Scissors) and classified the instrument as: “system, surgical, computer controlled instrument, remanufactured.”

153. FDA created the QSM product code as a result of the clearance of the Iconocare-remanufactured EndoWrist. The product code for the cleared Iconocare technology states: “The instrument has been remanufactured to extend its use life as compared to what was originally defined by the original equipment manufacturer.”

154. From an FDA regulatory perspective, the creation of the QSM code – and classification as a Class II device – by FDA means that FDA has determined that the extension of the use life for a surgical instrument for a computer controlled system, as compared to what was originally defined by the original manufacturer, requires 510(k) clearance. FDA would not

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

create a new product code for an “unnecessary” 510(k); doing so requires extra administrative effort and levels of approval. This is further evidence that FDA requires 510(k) clearance to extend the use life for any EndoWrists.

- b) [Congress also reached the same conclusion for a similar industry and activity – reprocessing – and amended FDA’s governing statute to define premarket requirements for the reprocessors of devices labeled for single use.](#)

155. FDA’s regulation of reprocessing is informative to the issues here, particularly with respect to the reprocessing of single-use devices.

156. Extending the usage limit of EndoWrists beyond their intended limits is an activity very similar to SUD reprocessing. SUD reprocessors facilitate the reuse of instruments labeled for a single use to extend their “life” for additional uses.

157. Even FDA has identified EndoWrists as having similar characteristics to single-use devices and indicated that certain reprocessing guidance documents are relevant to the premarket notification requirements for a “reset” EndoWrist instrument.¹³⁰

158. “Reprocessing” refers to cleaning and sterilization of medical devices — for example, cleaning and sterilizing reusable medical devices between uses, consistent with the FDA cleared or approved instructions for use for the device, and cleaning or sterilizing devices originally labeled for single use only, i.e. single-use devices (“SUDs”).

159. Congress has addressed reprocessing with respect to single-use devices. Reprocessing a single-use device refers to reprocessing a device that is labeled by the OEM for single use for an additional use.

¹³⁰ REBOTIX155894 (Deficiency #2).

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

160. In 2002, Congress passed the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) to address reprocessing of SUDs.¹³¹ The MDUFMA legislation amended the FD&C Act, establishing new statutory requirements applicable to reprocessed SUDs, including labeling identifying the devices as reprocessed,¹³² submission of validation data in premarket notifications (510(k)s), as well as a submission like a PMA for Class III SUDs known as Premarket Report (PMR).¹³³

161. FDA defined the policy that firms and hospitals that are reprocessing SUDs are considered by FDA to be manufacturers and as such must comply with all of the following statutory and regulatory requirements, where applicable:¹³⁴

- Quality System Regulation (Section 520(f) of the Act; 21 CFR Part 820)
- Medical Device Reporting (Section 519 (a), (b) and (c) of the Act; 21 CFR Part 803)
- Registration and Listing (Section 510 of the Act; 21 CFR Part 807)
- Labeling (Section 502 of the Act; 21 CFR Part 801)
- Premarket Approval (including Premarket Reports for reprocessed single-use devices) Section 515 of the Act; 21 CFR Part 814)
- Premarket Notification (510(k)) (Sections 510, 513 ; 21 CFR Part 807)
- Medical Device Corrections and Removals (Section 519(f) of the Act; 21 CFR Part 806)

¹³¹ Medical Device User Fee and Modernization Act of 2002, PL 107–250, October 26, 2002, 116 Stat 1588; 21 U.S.C. § 360(o).

¹³² 21 U.S.C. § 352(u)(2).

¹³³ 21 U.S.C. § 360(o); FDA, Summary of the Medical Device User Fee and Modernization Act of 2002, <https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/summary-medical-device-user-fee-and-modernization-act-2002> (last accessed Jan. 18, 2023).

¹³⁴ CPG § 300.500 (Reprocessing of Single Use Devices), available at: <https://www.fda.gov/media/71769/download> (last accessed Jan. 17, 2023).

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

- Medical Device Tracking (Section 519(e) of the Act; 21 CFR Part 821).

162. Because FDA considers reproprocessors of SUDs to be manufacturers, those reproprocessors are subject to premarket and postmarket requirements, such as 510(k) notification. The applicability of the 510(k) requirement to reprocessed single-use devices is codified at 21 U.S.C. § 360(o), which specifies the type of data that must be included in the 510(k) for reprocessed devices:

(1) With respect to reprocessed single-use devices for which reports are required under subsection (k):

(A) The Secretary shall identify such devices or types of devices for which reports under such subsection must, in order to ensure that the device is substantially equivalent to a predicate device, include validation data, the types of which shall be specified by the Secretary, regarding cleaning and sterilization, and functional performance demonstrating that the single-use device will remain substantially equivalent to its predicate device after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification.

163. It should be noted that Congress did not *need* to revise the governing statute in order to impose premarket requirements on the SUD reproprocessors. However, Congress amended the regulation to define the requirements.

164. Here, Congress does not need to step in. As explained in Section IV.A, remanufacturing is already clearly defined in the regulations, which have the same force of law as the governing statute, and is subject to the premarket requirements.

4. Third parties engaging in extending or resetting the lives of EndoWrist instruments are remanufacturers under existing FDA regulation. Therefore, they were required to obtain 510(k) clearance.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

- a) The activities that the third parties undertake to extend the usage limits significantly change the performance specifications of EndoWrist instruments.

165. An essential part of the design for the EndoWrist instruments is the limitation on the number of times each instrument may be used for surgical procedures. As I understand, the limitation is implemented through an integrated circuit that tracks the number of times an instrument is used by a da Vinci robot.¹³⁵

166. As I understand, during manufacturing, the chip is programmed with the total number of allowed uses; for most S and Si EndoWrist instruments, this usage limit is ten surgical procedures. When an instrument is connected to the robot, the chip in the instrument communicates with the robot, and a use is decremented. Once the uses have been decremented to zero, the robot will not activate the instrument.¹³⁶

167. As explained above in Section IV.B.1(a)-(f), this information was provided to and evaluated by FDA, which cleared the EndoWrist as a limited use device.

168. As I understand, the change that third parties are making or attempting to make is to the number of uses as specified in the labeling for the devices from the OEM by modifying or replacing the OEM counter to allow uses beyond the OEM limit.

169. There are two technologies that I am aware of that have been developed in order to remove and/or extend the usage limitation on EndoWrist instruments.

¹³⁵ Expert Report of Dr. Robert D. Howe (Aug. 20, 2021) (*Restore Robotics LLC et al. v. Intuitive Surgical, Inc.*) (“Howe Report (*Restore*)”) ¶ 25.

¹³⁶ Howe Report (*Restore*) ¶ 25.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

170. It is my understanding that in order to bypass the usage counter on EndoWrist instruments, SIS facilitated a “reset” service involving technology from Rebotix Repair LLC (“Rebotix”) called the “Interceptor.” SIS has not performed the reset process itself, but instead relied entirely on Rebotix to actually perform the reset.¹³⁷ SIS intends to begin resetting instruments pursuant to the Rebotix process at some point in the future.¹³⁸

171. It is my understanding that SIS’s facilitation involved collecting from hospitals used EndoWrist instruments and sending them to Rebotix in Florida to perform the “reset” process.¹³⁹ I also understand that, for a period, Restore Robotics Repair also performed the reset on behalf of Rebotix out of a facility in Anaheim, CA.¹⁴⁰

172. As I understand, Rebotix’s method intercepts communication between the robot and the instrument. During the process, the device is opened by brute force, the original circuit board is removed, the OEM chip is desoldered to remove it, and then it is soldered onto the Interceptor board. The Interceptor technology allows the third party to substitute an altered number of uses to allow the instrument to exceed the original, cleared usage limit.¹⁴¹

¹³⁷ Expert Report of Dr. Robert D. Howe (Dec. 2, 2022) (*Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc.*) (“Howe Report (SIS)”) ¶¶ 8, 34; 30(b)(6) Deposition of Greg Posdal (Nov. 1, 2022), Tr. 21:17-24, 22:10-12; 30(b)(6) Deposition of Keith Johnson (Oct. 27, 2022), Tr. 33:22-34:4.

¹³⁸ Phillips Report ¶ 94.

¹³⁹ Howe Report (SIS) ¶ 8.

¹⁴⁰ Deposition of Kevin May (Nov. 3, 2022), Tr. 105:14-22.

¹⁴¹ Howe Report (SIS), ¶¶ 35-36.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

173. This process for resetting the usage counter has never been cleared by FDA. As discussed above in Section IV.B.1(g), Rebotix sought out 510(k) clearance but later abandoned such an effort.

174. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]¹⁴²

175. As discussed above in Section IV.B.1(h), FDA reviewed this process as it is applied to Si 8mm Monopolar Curved Scissors and granted 510(k) clearance to Iconocare for remanufactured Si 8mm Monopolar Curved Scissors. FDA cleared Iconocare to only perform the reset process once on any given instrument, and this process has not been cleared by FDA to be used to reset any other instrument.

176. The third parties do not “return[the finished device] to the safety and performance specifications established by the OEM and to meet its original intended use.”¹⁴³ Because their activities significantly change the device’s performance specifications, their activities are considered by the FDA to be remanufacturing.

177. As discussed above, the Rebotix (and Iconocare) processes include a method that alters the performance specifications of the EndoWrists. The Rebotix

¹⁴² Restore-00089490, at -9495, -9498; Supplemental Expert Report of Dr. Robert D. Howe (Dec. 23, 2022) (*Restore*) (“Howe Supplemental Report (*Restore*)”), ¶¶ 144-45.

¹⁴³ FDA, “White Paper: Evaluating Whether Activities are Servicing or Remanufacturing” (December 2018), at 19, available at <https://www.fda.gov/media/117238/download> (last accessed Jan. 17, 2023); 21 CFR 820.3(w) (defining remanufacturer as a person who “dos any . . . act to a finished device significantly changes the finished device's performance or safety specifications, or intended use”); Phillips ¶¶ 84, 96.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

“Interceptor,” which replaces the original circuit board in the instrument and manipulates the data on the original chip, intercepts communication between the robot and the instrument and extends the performance of an EndoWrist beyond the original specified uses. The Iconocare process similarly changes the performance specifications through a process which replaces both the circuit board and the Dallas chip in order to bypass the originally-specified usage limits.

178. It is beyond dispute that the EndoWrist instruments sold by Intuitive are designed and manufactured to perform for the specified number of uses, which have been reviewed and cleared by FDA. By removing or extending the usage limitation, the third parties are significantly changing the performance of the instrument.

179. Such an activity constitutes remanufacturing and is therefore subject to the 510(k) premarket requirements.

- b) [The activities that the third parties undertake to extend the usage limits significantly change the safety specifications of EndoWrist instruments.](#)

180. The third parties' processes also significantly change the safety specifications. The EndoWrist instruments were evaluated by Intuitive to determine the bounds of safe and reliable use and reprocessing of each instrument and assigned the usage limitations accordingly. By extending the usage limits, the third parties are changing the safety specifications beyond what was originally validated by the original equipment manufacturer.

181. FDA has explained that changes to the reprocessing of the EndoWrist devices require a 510(k) because a System, Surgical, Computer controlled Instrument (product code NAY), which is how FDA classifies EndoWrists, poses a greater likelihood of microbial transmission and represents a high risk of infection if it is not adequately reprocessed.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

Extending the lives of an EndoWrist instrument necessarily involves changing the reprocessing instructions (by allowing additional reprocessing cycles beyond what was validated). “A 510(k) to change the reprocessing instructions of a cleared EndoWrist requires a new 510(K) submission for FDA to evaluate substantial equivalence.”¹⁴⁴

182. As such, by removing or extending the usage limitation, the third parties are significantly changing the safety specifications of the instrument.

183. Phillips seems to draw conclusions from the fact that there are no adverse events reported in the MAUDE database involving EndoWrist devices that include references to the third parties.¹⁴⁵ However, this has no relevance to FDA’s evaluation of whether an activity “significantly changes the finished device’s . . . safety specifications,” and Phillips’s argument is misleading.

184. First, it is important to understand FDA’s adverse event reporting requirements. FDA uses Medical Device Reporting (MDR) as a postmarket surveillance tool to “monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products.”¹⁴⁶

185. Certain entities are mandatory reporters. For example, “device user facilities” are required to report a suspected medical device-related death to both the FDA and

¹⁴⁴ Intuitive-00705778, at -5779.

¹⁴⁵ Phillips Report ¶ 112.

¹⁴⁶ FDA, Medical Device Reporting (MDR): How to Report Medical Device Problems, <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems> (last accessed Jan. 17, 2023).

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

the manufacturer and serious injuries to the manufacturer.¹⁴⁷ A device user facility is a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility, which is not a physician's office.¹⁴⁸

186. Manufacturers are also “mandatory reporters.” They are required to submit to FDA certain types of reports for adverse events and malfunctions associated with medical devices. Specifically, manufacturers are required to report to FDA when they learn that any of their devices “may have caused or contributed to a death or serious injury” and when they become aware that their device has malfunctioned and “would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.”¹⁴⁹

187. Because remanufacturers are considered by FDA to be manufacturers, they are fully responsible for compliance with all FDA requirements for manufacturers, including submitting MDRs to inform FDA of adverse events and malfunctions with the potential to cause harm associated with their remanufactured devices.¹⁵⁰

188. FDA records mandatory reports filed by manufacturers and importers from August 1996 to present on the Manufacturer and User Facility Device Experience (MAUDE) database. The MAUDE database houses MDRs submitted to the FDA by mandatory

¹⁴⁷ 21 CFR § 803.10(a).

¹⁴⁸ 21 CFR § 803.3(d).

¹⁴⁹ 21 CFR § 803.10(c); 21 CFR § 803.3(o); 21 CFR § 803.50.

¹⁵⁰ 21 CFR § 803.50.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers.¹⁵¹

189. If a manufacturer does not comply with its duty to report or believes it has no duty to report, then no reports would appear in the MAUDE database.

190. Similarly, if an entity is remanufacturing the original manufacturer's devices without complying with FDA's requirements for manufacturers, including registration, premarket notification, and reporting, then any adverse events associated with the remanufactured instrument would only appear as associated with the original manufacturer.

191. Even where a remanufacturer has complied with FDA's regulatory requirements, users, including hospitals, may continue to report reportable events to the original manufacturer.

192. Second, the absence of reported safety issues associated with a device does not affect the FDA's determination of whether an activity being performed on the device significantly affects the safety *specifications* of the device.

193. As discussed above in Section III.C.1, FDA's focus is on whether the activity in question *could* significantly affect the safety or effectiveness of the device. The absence of adverse events doesn't necessarily have a direct bearing on this assessment in my experience. But the presence of adverse events could have an impact.

- c) [The third parties are introducing new devices into interstate commerce, which makes their activity subject to FDA requirements.](#)

¹⁵¹ FDA, Medical Device Reporting (MDR): How to Report Medical Device Problems, <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems> (last accessed Jan. 17, 2023).

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

194. It is worth also noting that FDA regulatory requirements apply where the product has been introduced into interstate commerce. In my experience preparing cases for FDA, interstate commerce could be established by the transport of a finished device across state boundaries or it could be established by the transport of components or products across state boundaries that are then used in the finished device.

195. Section 201(b) of the FD&C Act [21 U.S.C. 321(b)] tells what circumstances place a product in interstate commerce:

"(1) commerce between any State or Territory and any place outside thereof, and

(2) commerce within the District of Columbia or within any other Territory not organized with a legislative body."

196. According to the FDA website:¹⁵²

"Interstate commerce" applies to all steps in a product's manufacture, packaging, and distribution. It is very rare that a cosmetic product on the market is not in "interstate commerce" under the law. For example, at least some of your ingredients or packaging most likely originate from out of state, or even out of the country. Likewise, it is foreseeable that your products will leave the state.

197. While the above paragraph speaks to cosmetic products, FDA uses the same definition for interstate commerce for all of its regulated products (drugs, devices, biologics, foods, etc.).

¹⁵² FDA, Key Legal Concepts for Cosmetics Industry: Interstate Commerce, Adulterated, and Misbranded, <https://www.fda.gov/cosmetics/cosmetics-laws-regulations/key-legal-concepts-cosmetics-industry-interstate-commerce-adulterated-and-misbranded> (last accessed Jan. 17, 2023); 21 U.S.C. § 321(b).

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

198. Utilizing these principles, the activities conducted would meet FDA's definition of interstate commerce in my experience and opinion.

199. There is evidence that SIS, Rebotix, and Restore have all introduced these remanufactured devices into interstate commerce. The third parties have shipped or facilitated the shipping of remanufactured EndoWrists to hospitals in Texas, New York, Massachusetts, Arkansas, and other states from their locations in California and Florida.¹⁵³

d) The third parties' arguments that they are not remanufacturers are incorrect.

200. What the third parties do is in fact remanufacturing. There is no ambiguity on this point, and Intuitive was correct in its belief that the third parties' activities violated FDA regulations. Moreover, SIS's decision to engage in these activities without 510(k) clearance was unreasonable.

201. As explained above, a remanufacturer is a person who engages in acts "to a finished device that significantly changes the finished device's performance or safety specifications, or intended use." And as demonstrated in Sections IV.A.B.4(a) and (b), the activities at issue here significantly change the device's performance and safety specifications.

202. FDA's Center for Devices and Radiological Health (CDRH) is "responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices sold in the United States." CDRH's focus is on the underlying activity, not who the firm is.

203. Whether an entity self-describes as a "repair" company does not change the nature of their activities.

¹⁵³ REBOTIX175326; Restore-00055935; Restore-00055937.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

204. Similarly, whether or not a “repair” company takes title of the instrument or sells the instrument to a different hospital is not relevant to a determination that the activity is remanufacturing. Under FDA’s existing regulations, ownership of a medical device does not impact a regulatory determination. That determination is driven by the particular activity being performed on the device.

205. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].

206. Any entity that engages in the activities described in FDA’s definition of remanufacturing is a remanufacturer, regardless of title, ownership, or whether that entity identifies as a repairer or servicer.

¹⁵⁴ Phillips Report ¶ 82. Restore’s Kevin May testified that the “repair” and “remanufacturing” processes expected to be employed by Iconocare are the same activity. He testified that the difference between the two is that Iconocare will comply with FDA’s labeling requirements when Iconocare sells the instruments but will not comply if Iconocare does not take ownership of the device. May Tr. 80:8-14; 102:4-7. Moreover, he testified that Iconocare could use the process to reset *any* instrument any number of times for the same reasons. May Tr. 137:23-140:4. This is in direct violation of FDA’s regulations and FDA’s own directive to Restore. K210478 510(k) Summary (“Please be advised that FDA’s issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act’s requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices . . .”).

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

207. In 1998, FDA revoked Compliance Policy Guide (CPG) 7124.28, Reconditioners/Rebuilders of Medical Devices,¹⁵⁵ “because application of [then-]current good manufacturing practice (CGMP) requirements to ‘reconditioners/rebuilders’ of used medical devices [did] not comport with definitions in the quality system (QS) regulation or guidance in the final rule that applies CGMP requirements to ‘manufactures’ and ‘remanufacturers.’”¹⁵⁶

208. Before the revocation, CPG 7124.28 interpreted Section 510 of the Act and defined a “reconditioner/rebuilder” as a “person or firm that acquires ownership of a used device and, for purposes of resale or commercial distribution, “restores” or “refurbishes” the device to the manufacturer’s original or current specifications, or new specifications.”¹⁵⁷

209. However, after the new term “remanufacturer” was added to 21 CFR 820 and defined, as above, in 21 CFR 820.3(w), FDA determined that the guidance in CPG 7124.28 had become obsolete because its terminology and application of CGMP requirements no longer conformed with the terms and applicability of the regulations.¹⁵⁸

210. FDA explained: “FDA no longer believes that the processing, remarketing, or servicing of used devices should be characterized in terms of whether or not the processor acquires ownership of the device for purposes of resale or remarketing.”¹⁵⁹ FDA indicated that this decision was made “on the basis of industry concerns raised during CGMP rulemaking,

¹⁵⁵ CPG 7124.28 was issued on December 29, 1987 and revised in March 1995.

¹⁵⁶ 63 Fed. Reg. 67076 (Dec. 4, 1998).

¹⁵⁷ *Ibid.*

¹⁵⁸ *Ibid.* at 67077.

¹⁵⁹ *Ibid.*

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

FDA's knowledge of changes in the used-device market, and information on used-device 'remarketers' and 'servicers' obtained through the International Association of Medical Equipment Remarketers."¹⁶⁰

211. FDA explained that the more important distinction was "between the types of processing conducted on used devices ***on the basis of whether or not significant changes occur, or are made, in the performance or safety specifications or intended use of the finished device, as a result of the processing.***"¹⁶¹

212. Notably, FDA's revocation of this distinction came after advocacy from SUD reprocessors, who argued that reprocessors "differ significantly" from refurbishers, "as is" remarketers, services, and reconditioners/rebuilders in part *because* "the hospital retains ownership," and reprocessors never "acquire ownership of medical devices" or "resell or commercially distribute devices."¹⁶²

213. Despite this advocacy, FDA rejected this argument, deciding that its focus was on "used-device processors making significant modifications to finished devices," regardless of whether the entity held title or acquired ownership to the device.¹⁶³

214. FDA has not revoked or changed this guidance.

215. Phillips points out that FDA anticipated issuance of a rule or further guidance setting forth the agency's current position on the applicability of regulatory

¹⁶⁰ Ibid.

¹⁶¹ Ibid. (emphasis added)

¹⁶² See, e.g., Letter from Counsel to the Association of Medical Device Reprocessors to FDA (Mar. 23, 1998)

¹⁶³ 63 Fed. Reg. 67076 at 67077.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

requirements to “reconditioners/rebuilders” of used devices¹⁶⁴ but “has not promulgated a regulation pertaining to the ‘used device market’ and no guidance document outlining the Agency’s thinking on the matter is in effect.”¹⁶⁵ However, the lack of a final rule or further guidance on “reconditioners/rebuilders” is irrelevant to FDA’s conclusion that entities whose activities significantly change the performance or safety specifications, or intended use of a finished device are remanufacturers (and therefore manufacturers), subject to applicable regulatory requirements, including premarket notification, regardless of whether they take ownership of the subject device.

216. Because the third parties were remanufacturing EndoWrist instruments, a 510(k) clearance was required, and SIS’s decision to not pursue 510(k) clearance for these activities had no basis in a reasonable interpretation of the law.

C. Opinion 3 – FDA communicated to certain third parties that their activities constituted remanufacturing.

217. FDA has told Iconocare, Restore, and Rebotix that resetting or extending the usage limits beyond their cleared limit constitutes remanufacturing.

218. First, as explained in Section IV.B.1(g), Rebotix applied for 510(k) clearance in 2014 and later withdrew that application after receiving a 51-item deficiency letter from FDA, indicating that FDA required additional information and data from Rebotix before it could determine that Rebotix’s “re-manufactured” EndoWrists could be safely used. Rebotix

¹⁶⁴ Ibid. at 67078.

¹⁶⁵ Phillips Report ¶ 59.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

cited the nature of the testing and information requested” by FDA as the reason for its decision to withdraw the submission.¹⁶⁶

219. In the June 2015 deficiency notification to Rebotix, FDA stated clearly that the remanufactured EndoWrists could not be marketed until Rebotix had received a letter allowing it to do so: “If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.”¹⁶⁷

220. Phillips suggests that this boilerplate language “means nothing” when a 510(k) is “unnecessary.” As I explained above in Section IV.B.1(g), FDA does not make a practice of investing the time and resources required to identify 51 deficiencies in a 510(k) submission it considers “unnecessary.” And more importantly, whether or not the language in the deficiency that Rebotix may not market the remanufactured EndoWrists without a 510(k) is “boilerplate” does not diminish its weight as a determination by FDA. FDA expects that its determinations will be complied with and would not include such language if it did not.

221. Second, on May 21, 2018, Bob Overmars, President and CEO at BPI Medical, e-mailed Dr. Cal F. Rabang, a biomedical engineer who works at FDA in [CDRH/ODE/DSD/GSDB2] inquiring (on behalf of Rebotix) why FDA was “concerned” about the so-called repair companies having a 510(k), arguing that BPI “repair[s] 1000’s of reusable Endoscopic Instruments and the FDA does not require a 510K to repair those.”¹⁶⁸ Dr. Rabang responded on June 6, 2018:

¹⁶⁶ REBOTIX171076.

¹⁶⁷ REBOTIX171058.

¹⁶⁸ BPI000331, at BPI000336.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

§ Specifically for the reusable Endowrist Instruments, if the use-life counter is reset or extended past the number of available use lives, then the device specifications are changed. As such, you would be considered a remanufacturer per 21 CFR 820.3(w). In addition, if during the repair process the device is cleaned, disinfected and/or sterilized, then you would be considered a 3rd party reprocessor.

§ Remanufacturers and 3rd Party Processors meet the definition of "manufacturer" specified in 21 CFR 820.3(o) and are required to register and list according to 21 CFR 807.20. In addition, Endowrist Instruments are classified as Class II devices per 21 CFR 876.1500, Product Code NAY. As such, you would be subject to premarket notification (510(k)) requirements defined in 21 CFR 807.81.

I hope this provides enough explanation regarding the 510(k) requirements for repair of da Vinci reusable Endoscopic Instruments.¹⁶⁹

222. Overmars forwarded this e-mail to Glenn Papit at Rebotix, who forwarded the same to Chris Gibson and Stan Hamilton, who I understand to have been employees at Rebotix.¹⁷⁰ In response, Hamilton explained that there was “no need to respond” to FDA because it would be “revisiting the path that Rebotix went down in some agonizing detail over 2 years ago.”¹⁷¹

223. [REDACTED]

[REDACTED]

[REDACTED]

¹⁶⁹ Ibid. at BPI000335.

¹⁷⁰ Ibid. at BPI000334.

¹⁷¹ Ibid. at BPI000333.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

[REDACTED]

[REDACTED].¹⁷²

224. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED]:

[REDACTED]

¹⁷² REBOTIX146948, at -6955; Restore-00001248, at -1256.

¹⁷³ Restore-00001248, at -1254 (emphasis added)

¹⁷⁴ Ibid (emphasis added).

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

225. Rebotix made the same argument to FDA and received the same response and list of questions.¹⁷⁵ FDA clearly communicated its position to both Restore and Rebotix that FDA was concerned that the underlying activity constituted remanufacturing without clearance, regardless of the ownership of the device.

226. FDA told Rebotix in November 2021 again that its activities constituted remanufacturing. On November 16, 2021, Intuitive sent a "It Has Come To Our Attention" letter, explaining that FDA received information that Rebotix "may be remanufacturing the da Vinci S EndoWrist Instruments."¹⁷⁶

227. In certain situations, CDRH may become aware that regulated industry may be promoting a medical device in a manner that potentially violates the Federal Food, Drug, and Cosmetic Act and its implementing regulations. CDRH may issue an "It Has Come to Our Attention" Letter (IHCTOA Letter) to regulated industry as an early communication to gather additional information. An ICHTOA Letter can be a precursor to an enforcement action if FDA does not obtain a response that alleviates FDA's concerns.¹⁷⁷

228. In this letter, FDA explained that it conducted a review of its file and had "been unable to identify any Food and Drug Administration (FDA) clearance approval number

¹⁷⁵ REBOTIX146948, at -6952-6954. Rebotix responded to FDA's e-mail with responses on March 19, 2020. Ibid. at -6948-6952. Restore never provided any responses to FDA's questions but instead represented that it had ceased all activity on EndoWrist instruments. Restore-00001248, at -1249.

¹⁷⁶ REBOTIX175417.

¹⁷⁷ FDA, Letters to Industry, <https://www.fda.gov/medical-devices/industry-medical-devices/letters-industry> (last accessed Jan. 17, 2023).

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

for the da Vinci S EndoWrist Instruments to support the services described on your website . . . and described in a prior email communication to the Agency dated March 19, 2020.”¹⁷⁸

229. FDA continued: “Specifically, the da Vinci S EndoWrist Instruments were cleared for a set number of uses. By extending the number of uses, your activities may be altering the intended use of the subject device.”¹⁷⁹

230. Rebotix responded to FDA’s letter on January 13, 2022, reiterating its argument that it does not take ownership of the devices and therefore cannot be a remanufacturer, and that it had not sought FDA clearance or approval “because it is not required to do so.”¹⁸⁰

231. On April 6, 2022, Anthony Lee, a Team Lead on the Robotic-Assisted Surgery Devices Team in CDRH at FDA, informed Rebotix that a decision had been made in relation to the It Has Come To Our Attention letter. On April 8, Lee e-mailed Rebotix, writing, “As mentioned during our call, the Agency believes that the activities of Rebotix constitute remanufacturing and would require FDA review and clearance (e.g. 510(k) / de Novo). We therefore request that Rebotix stop engaging in the current activities until an application is reviewed and cleared/granted.”¹⁸¹

232. Lee explained, “The instruments in question no longer maintain the same safety and effectiveness profile as cleared with the original manufacturer’s own submission. During premarket review, FDA reviews test data to the labeled number of reuse cycles. . . . **By**

¹⁷⁸ REBOTIX175417.

¹⁷⁹ Ibid.

¹⁸⁰ REBOTIX175468.

¹⁸¹ REBOTIX175710, at -5726-28.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

extending the number of uses and modifying the instrument with a new chip, the prior information is no longer valid and requires additional review to the new labeled usage limit in order to establish safety and effectiveness. This is therefore different than returning the device to its original condition."¹⁸²

233. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]¹⁸³

234. However, it is my opinion that the information was being communicated by the reviewer. The reviewer offers opinions. It appears from the documents that Rebotix was contemplating appealing FDA's decision, and it is my opinion that the reviewer was trying to indicate that this opinion was not subject to a supervisory appeal under 21 CFR 10.75. Moreover, the communication ended with a suggestion that, if Rebotix wanted to take this further, they should submit a 510(k). Rebotix's other option would have been a 513(g), which they did not pursue. All of this indicates that FDA had not deviated from its position that a 510(k) was needed, and Rebotix never took any formal steps to seek a final, different decision on that.

¹⁸² Ibid. at -5727 (emphasis added)

¹⁸³ Ibid. at -5839.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

235. It is my opinion that the reviewer's opinion is consistent with the review practices observed from the 510(k) reviews that did receive management sign-off as well as the creation of the product code which would have required even more levels of management sign-off.

D. Opinion 4 – Intuitive has acted in accordance with FDA's requirements for the marketing and sale of its devices and has not unreasonably interpreted FDA's existing regulations and guidance.

1. Intuitive's marketing and sale of EndoWrist instruments with usage limits is consistent with FDA's regulatory requirements.

236. First, FDA's 510(K) clearance of EndoWrist instruments requires Intuitive to market and sell those instruments in a manner consistent with the 510(k) including the usage limits identified in the submission and ultimately cleared by FDA.

237. A manufacturer is required to market and sell its device as it was cleared by FDA.¹⁸⁴ FDA recognizes, however, that medical devices undergo frequent modifications to their design and materials due to many things; changes in the supply chain, continuous process improvement, or to keep pace with technological innovations that can improve how these devices work in a clinical setting. Major modifications to the device likely require premarket review by the FDA, while minor changes likely do not.¹⁸⁵

238. As explained above in Section III.C.1, in accordance with 21 CFR § 807.81(a)(3), a premarket submission is required for a device that has been cleared, when a

¹⁸⁴ 21 CFR § 807.81(3); 21 U.S.C. § 352(o).

¹⁸⁵ FDA, Is A New 510(k) Required for a Modification to the Device?, <https://www.fda.gov/medical-devices/premarket-notification-510k/new-510k-required-modification-device> (last accessed Jan. 17, 2023).

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process, is made, or there is a major change or modification in the intended use of the device.

239. Therefore, Intuitive must market and sell its EndoWrist instruments with the usage limits that were validated for FDA clearance, or, if it chooses to make a change or modification for the device that could significantly affect the safety or effectiveness of the device, such as extending the number of lives for which an EndoWrist may be used, Intuitive must submit a new 510(k) for the changed or modified device.

240. As discussed further below, FDA has confirmed that it believes a new 510(k) is required for modifying the usage limits on EndoWrist instruments by requiring Intuitive to submit a “catch-up” 510(k) for extending the lives of certain X/Xi instruments beyond their cleared limits.¹⁸⁶

241. Additionally, FDA’s view is that the EndoWrist instruments have many aspects in common with third party reprocessed single-use devices.

242. As discussed above, in its June 2015 deficiency letter to Rebotix, FDA explained that EndoWrists are not single-use devices, but because they have many “aspects in common with third party reprocessed single-use devices,”¹⁸⁷ Rebotix should review and provide

¹⁸⁶ Consistent with my experience, FDA does not take enforcement action against a company who is actively making an effort to bring a product into regulatory compliance after being informed of a non-compliance.

¹⁸⁷ REBOTIX171030.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

the items described in FDA's guidance, "Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices."¹⁸⁸

243. FDA has also explained that extending the usage limits on EndoWrist instruments requires changes to the reprocessing instructions for the device and therefore recommended (to both Intuitive and Iconocare¹⁸⁹) reviewing FDA's March 2015 guidance document, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff."¹⁹⁰

244. This final guidance explains recommendations for the formulation and scientific validation of reprocessing instructions for reusable medical devices. This guidance document also provides recommendations for the content and review of premarket notification submissions [510(k)], premarket approval (PMA) applications, humanitarian device exemption (HDE) applications, *de novo* requests and investigational device exemption (IDE) applications, concerning the labeling instructions for reprocessing reusable medical devices.

245. As mentioned in Section IV.B.2, this guidance also includes the recommendation that reuse life may also be addressed by validating the number of times the product can be reprocessed and reused, and providing this specification in the labeling. If the reuse life of a device is limited to a specific number of use/reprocessing cycles, the labeling

¹⁸⁸ REBOTIX171030. This guidance is available at <https://www.fda.gov/media/71482/download> (last accessed Jan. 17, 2023).

¹⁸⁹ Intuitive-00705778, at -5779; AHP000527, at -0528.

¹⁹⁰ This guidance is available at <https://www.fda.gov/media/80265/download> (last accessed Jan. 17, 2023).

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

should also describe a specific tracking method for the number of reuse cycles.¹⁹¹ In my opinion, the counter that is included as part of the EndoWrist and similar devices would meet this recommendation.

2. Intuitive's cybersecurity measures are consistent with FDA expectations for devices that are vulnerable to cybersecurity threats.

246. The expert report provided by Kurt Humphrey suggests that the sole purpose for Intuitive's cybersecurity security protocols is to "thwart efforts by third-parties to reset the instrument's use counter."¹⁹²

247. In my experience submitting recent marketing applications to FDA, cybersecurity is an area of increased focus during the review of submissions.

248. If Intuitive did not have cybersecurity measures, FDA would generate major deficiencies that would need to be resolved.

249. Specifically, FDA did in fact raise cybersecurity questions during the review of K131861. This included a request for "*Cyber and Information security*

You mention network communications as part of this system. There is not a separate Section addressing the CyberSecurity issues. Please review the Management of Cybersecurity Guidance issued 6/14/13 and provide information, as appropriate, on the Cybersecurity aspects of your device.'

250. FDA specifically instructed Intuitive to review the following software guidance documents.¹⁹³

¹⁹¹ FDA, "Reprocessing Medical Devices in health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff," at 20.

¹⁹² Expert Report of Kurt Humphrey (Dec. 2, 2022) ¶ 60.

¹⁹³ Intuitive-00499468, at -9499-9500.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

- May 11, 2005 “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”, which is intended to provide information to industry regarding the documentation that FDA recommends entities include in premarket submissions for software devices, including standalone software applications and hardware-based devices that incorporate software.¹⁹⁴
- September 9, 1999 “Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices,” which represents the agency’s current thinking on the documentation that should be provided in premarket submissions for medical devices using off-the-shelf software;¹⁹⁵
- January 11, 2002 “General Principles of Software Validation; Final Guidance for Industry and FDA Staff,” which outlines general validation principles that FDA considers applicable to the validation of medical device software or software used to design, develop, or manufacture medical devices;¹⁹⁶
- January 14, 2005 “Guidance for Industry, Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software,” which outlines general principles that FDA considers to be applicable to software maintenance actions required to address cybersecurity vulnerabilities for networked medical devices;¹⁹⁷ and

¹⁹⁴ Available at <https://www.fda.gov/media/73065/download> (last accessed Jan. 17, 2023).

¹⁹⁵ Available at <https://www.inea.com/PDF/otssguid.pdf> (last accessed Jan. 17, 2023). This guidance has since been superseded by the guidance document, “Off-The-Shelf Software Use in Medical Devices,” which FDA issued on September 27, 2019, available at <https://www.fda.gov/media/71794/download> (last accessed Jan. 17, 2023).

¹⁹⁶ Available at <https://www.fda.gov/media/73141/download> (last accessed Jan. 17, 2023).

¹⁹⁷ Available at <https://www.fda.gov/media/72154/download> (last accessed Jan. 17, 2023).

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

- June 14, 2013 “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices - Draft Guidance for Industry and Food and Drug Administration Staff,” which was developed to assist industry by identifying issues related to cybersecurity that FDA believes manufacturers should consider in the design and development of medical devices, as well as in preparing premarket submissions for those devices.¹⁹⁸

251. In accordance with the June 2013 draft guidance on Management of Cybersecurity in Medical Devices, Intuitive responded with a cybersecurity hazard analysis, traceability matrix, maintenance plan, malware certification and device instructions. Additionally, they provided a cybersecurity and penetration validation protocol that evaluated the effectiveness of the company’s mitigations identified as part of the cybersecurity risk analysis.

252. According to the FDA website, Medical Device Manufacturers (MDMs) are responsible for remaining vigilant about identifying risks and hazards associated with their medical devices, including risks related to cybersecurity. Both MDMs and health care delivery organizations (HDOs) are responsible for putting appropriate mitigations in place to address patient safety risks and ensure proper device performance.¹⁹⁹

¹⁹⁸ Available at <https://www.regulations.gov/document/FDA-2013-D-0616-0002> (last accessed Jan. 17, 2023). The final version of this guidance was issued on October 2, 2014, and is available at <https://www.fda.gov/media/86174/download> (last accessed Jan. 17, 2023).

¹⁹⁹ FDA, Cybersecurity, <https://www.fda.gov/medical-devices/digital-health-center-excellence/cybersecurity> (last accessed Jan. 17, 2023).

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

253. Since December 2016, FDA has issued three guidance documents related to cybersecurity, with the requirements for premarket data supporting the mitigation of cybersecurity risks increasing in each version.²⁰⁰

254. The most recent draft issued on April 8, 2022 indicates that this draft guidance replaces the 2018 draft version and is “intended to further emphasize the importance of ensuring that devices are designed securely, are designed to be capable of mitigating emerging cybersecurity risks to be mitigated throughout the [Total Product Lifecycle], and to more clearly outline the FDA’s recommendations for premarket submission information to address cybersecurity concerns.”²⁰¹

3. Intuitive’s internal conduct does not contradict applicable FDA regulations and guidance, nor does it negate the duty of third-party companies to comply with existing FDA regulations and guidance.

255. I understand that Intuitive told customers and FDA that the activities of these third parties were remanufacturing EndoWrist instruments in violation of FDA regulations and guidance. As explained above, this was based on a reasonable interpretation of existing FDA regulations and guidance.

²⁰⁰ FDA, “Postmarket Management of Cybersecurity in Medical Devices” (Dec. 27, 2016), available at <https://www.fda.gov/media/95862/download> (last accessed Jan. 18, 2023); FDA, “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices” (Oct. 18, 2018) (draft guidance superseded by April 2022 draft guidance); FDA, “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions” (Apr. 8, 2022), available at <https://www.fda.gov/media/119933/download> (last accessed Jan. 18, 2023).

²⁰¹ FDA, “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions,” at 3.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

256. Phillips suggests that Intuitive “addressed the question” of whether extending the usage limit of an EndoWrist instrument beyond what was cleared by FDA required submission of a 510(k) and concluded that it did not.²⁰² However, Phillips is wrong, and his argument misstates the underlying reality: it is FDA who determines whether 510(k) clearance is needed, and FDA has determined that 510(k) clearance is required to extend the lives of EndoWrist instruments that were cleared with prescribed usage limits.

257. Phillips points to Intuitive’s determination that Intuitive, as the original equipment manufacturer, could extend lives without 510(k) clearance using a non-filing justification (NFJ).²⁰³

258. As discussed above in Section III.C.1, a manufacturer who has a device in commercial distribution that is about to be significantly changed or modified must submit a new 510(k). To assist manufacturers in determining whether a new 510(k) is required for a change, FDA has released certain guidance documents.²⁰⁴

259. Intuitive’s decision to not file a new 510(k) for the extended lives instruments was based on the FDA guidance document, “Deciding When to Submit a 510(k) for a Change to an Existing Device.”²⁰⁵ This guidance applies to “manufacturers of medical devices

²⁰² Phillips Report ¶¶ 105–06.

²⁰³ Ibid. ¶ 106.

²⁰⁴ FDA, “Deciding When to Submit a 510(k) for a Change to an Existing Device” (Oct. 25, 2017) (originally issued Jan. 10, 1997), available at <https://www.fda.gov/media/99812/download> (last accessed Jan. 17, 2023); FDA, “Deciding When to Submit a 510(k) for a Software Change to an Existing Device” (Oct. 25, 2017), available at <https://www.fda.gov/media/99785/download> (last accessed Jan. 17, 2023).

²⁰⁵ Intuitive-00705587.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

subject to premarket notification requirements who intend to modify a 510(k)-cleared device (or group of devices) or other device subject to 510(k) requirements.”²⁰⁶ Notably, this guidance applies only to Intuitive as the manufacturer, not to remanufacturers such as Restore, Rebotix, SIS, or Iconocare Health.

260. Intuitive applied the existing guidance to the changes it, as the original equipment manufacturer, made to the EndoWrist instruments and concluded that a NFJ was appropriate and that a 510(k) submission was not necessary. This was not an unreasonable conclusion under the applicable guidance.

261. The 510(k) modifications guidance utilizes flowcharts to aid in the decision making process. The Flowcharts most applicable to this circumstance would be Flowchart A (Labeling Changes) and B (Technology, Engineering, and Performance Changes). A specific consideration in Flowchart A includes:

Changes in frequency or duration of use: Changes in the frequency or duration of use of a device include changes indicating that a device can or should be used more or less often, changes indicating that a device can perform a task or treat a condition in or for a different duration of time, or changes between periodic and continuous monitoring. Manufacturers should evaluate the effect such changes could have on the performance of a device, and whether such changes significantly affect the device’s risk profile.

²⁰⁶ “Deciding When to Submit a 510(k) for a Change to an Existing Device,” at 6.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

262. However, what is more relevant to this case is that FDA determined that even Intuitive could not extend lives without seeking 510(k) clearance. FDA informed Intuitive that it would need to submit a "catch-up" 510(k) to continue marketing and selling X/Xi instruments with extended lives.²⁰⁷

263. FDA specifically informed Intuitive of the following major deficiency in an additional information request letter for K212101²⁰⁸:

"You replied that these changes were made between K173906 and the current submission without 510(k) clearance on the basis of FDA guidance "Deciding When to Submit a 510(k) for a Change to an Existing Device" and internally documented Non-Filing Justifications 1048606-02 (endoscope version -41), 1048620-01 (reprocessing instructions - sterilization trays), and 1048620-02 (reprocessing instructions - number of uses).

However, we believe that changes to the reprocessing of your device require a 510(k). Your device falls under the Endoscope and Accessories regulation (21 CFR 876.1500). Per Appendix E of FDA's guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," a System, Surgical, Computer Controlled Instrument (product code NAY) poses a greater likelihood of microbial transmission and represents a high risk of infection if it is not adequately reprocessed. Because of the greater risks to the public health posed by these devices, 510(k) submissions should include protocols and complete test reports of the validation of the reprocessing instructions for us to evaluate substantial equivalence. Therefore, even if the endoscope validation testing was performed using similar test methodology as described in a previous 510(k) submission, the new

²⁰⁷ Consistent with my experience, FDA does not take enforcement action against a company who is actively making an effort to bring a product into regulatory compliance after being informed of a non-compliance.

²⁰⁸ Intuitive-00705778, at 5779–81.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

reprocessing validation information needs to be included in a 510(k) submission for FDA review.

Please provide the testing and data requested below:"

264. The deficiency letter continued to list five related topics that the company should address or alternatively revise the labeling to reflect the number of uses and reprocessing instructions that have been previously cleared.

265. FDA continues on to state that "this is needed to ensure that the system instruments, cameras and sterilization trays can be used safely and effectively for the number of uses proposed in Appendix A of your reprocessing instructions."

266. It is worth noting that FDA would not require only the original equipment manufacturer, who has the complete Device History Record and access to the original validation data, to submit a 510(k) to extend the usage limits beyond the cleared limits on its own devices but then *not* require a wholly independent third party performing the same actions to comply with those same requirements for a device it did not originally manufacture. Such a double standard would be untenable.

267. Phillips suggests that because Intuitive concluded in the NFJs for extending the lives of certain X/Xi EndoWrist instruments that the extension did not "significantly change the finished device's performance or safety specifications, or intended use,"²⁰⁹ it was reasonable for SIS to believe that its resetting the usage counter to increase the

²⁰⁹ Phillips Report ¶¶ 105-06.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

number of lives does not significantly affect the safety or effectiveness of the EndoWrist.²¹⁰ This is false.

268. Intuitive's determination that the extension of usage limits on the selected instruments did not involve any design changes that significantly affected the device's performance or safety specifications, or intended use, because Intuitive had made several incremental design changes prior to this NFJ that led the engineers to conclude that was safe to extend the lives.²¹¹ Each of those NFJs and accompanying changes is reflected in the extended lives NFJs.²¹²

269. Finally, I understand that at the point that Intuitive determined it could extend the lives on the EndoWrists (and still today), third parties did not have the capability to extend lives of X/Xi instruments.²¹³ Intuitive never concluded that it was safe to extend the lives of S/Si instruments, which is the activity the third parties engaged in.

v. Conclusion

270. Based on my review of the activities conducted on the Intuitive Surgical EndoWrist devices, I believe those activities meet the definition of remanufacturing as defined by FDA. Additionally, based on Agency actions as well as the descriptions provided in submitted 510(k)s, FDA considers these activities to be remanufacturing, as do the submitters of the 510(k)s who clearly describe the practice of extending the life of the instruments as

²¹⁰ Phillips Report §§ V.A.–B.

²¹¹ Deposition of Disha Peswani (Oct. 6, 2022), Tr. 113:11-116:13.

²¹² E.g. Intuitive-00552632, at -2641–51.

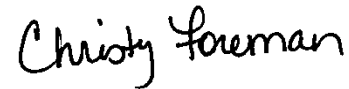
²¹³ Deposition of Stan Hamilton (Nov. 4, 2022), Tr. 14:25-15:6, 38:9-15; Deposition of Kevin May (Nov. 3, 2022), Tr. 40:21-23.

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

remanufacturing. I believe that these activities are permissible provided there is a valid 510(k) with supporting data to demonstrate that the remanufactured devices are substantially equivalent to the predicate Intuitive devices FDA has cleared.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: January 18, 2023



Christy Foreman, MBE

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

Appendices

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

Appendix A – Curriculum Vitae of Christy Foreman

Christy Foreman, MBE Senior Consultant

Biologics Consulting Group, Inc.

1555 King Street, Suite 300 • Alexandria, VA 22314

Phone: 703.739.5695 • Fax 703.548.7457

Email: cforeman@biologicsconsulting.com

PROFESSIONAL SUMMARY

More than 30 years experience as a biomedical engineer with over 28 years of federal experience and 22 years of FDA experience, including experience with premarket submissions (510(k)s, PMAs, IDEs, HDEs, de novos, preSubs and 513(g)s as well as cGMP/Quality Systems for medical devices.

EXPERIENCE

Biologics Consulting Group, Inc., Senior Consultant, Alexandria, VA (Apr 2018 – Present)

- Advises clients on short and long term regulatory strategies for medical devices and combination products
- Assists in the development of Quality Systems
- Prepares medical device regulatory submissions, including 510(k), PMA, HDE, RFD, 513(g), preSub, and IDE
- Represents clients in interactions with FDA; assists clients in the preparation for Advisory Panel meetings
- Provides in-house training on FDA Regulatory issues and new policy developments

Food and Drug Administration (FDA)/Center for Tobacco Products Office of Compliance and Enforcement, Associate Director for Regulatory Programs, Silver Spring, MD (Sept 2014 – Apr 2018)

- Developed foundational regulations, including manufacturing practice regulations for tobacco products. Developed and established novel regulatory programs for the newest FDA center, including the No-Tobacco Sale Order Program, a novel enforcement tool for egregious violators of the Food, Drug

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

- and Cosmetic Act
- Developed guidance documents, webinars and training programs

FDA/Center for Devices and Radiological Health (CDRH) Office of Device Evaluation (ODE), Office Director, Silver Spring, MD (Mar 2010 – Sept 2014)

- Oversaw a staff of 500+ scientists and clinicians conducting the regulatory review of applications including 510(k)s, PMAs, IDEs, HDEs, preSubs, PDPs, De Novos and 513(g)s, as well as consults for combination products in NDAs and BLAs and decided all office level appeals
- Participated in user fee negotiations with industry, implemented the user fee commitments into the regulatory review programs and implemented new legislation (FDASIA)
- Instrumental in developing regulatory improvements through the 510(k) Plan of Action

FDA/CDRH/ODE, Deputy Office Director for Science and Review Policy, Silver Spring, MD (June 2008 – Mar 2010)

- Served as the chief scientific officer for the office
- Oversaw the regulatory policies associated with 510(k), PMA, HDE, IDE, de novo and 513(g) programs as well as combination products
- Provided office-level review and sign-off for guidance documents, de novo submissions and 513(g)s

FDA/CDRH/Office of Compliance (OC)/Division of Enforcement B, Deputy Division Director, Silver Spring, MD (Dec 2002 – Dec 2008)

- Planned, organized, developed, and evaluated programmatic operations supporting the enforcement of the Federal Food, Drug and Cosmetic Act related to cardiovascular, neurology, orthopedic, physical medicine, anesthesiology and radiology devices and radiological health products such as microwaves and laser products
- Oversaw significant enforcement actions, including a seizure, several injunctions and supported criminal cases and served as an FDA expert witness for failures to comply with the Quality System Regulations Developed guidance documents for requirements for manufacturing information for PMAs

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

FDA/CDRH/OC/Division of Enforcement B/ Orthopedic, Physical Medicine and Anesthesiology Device Branch, Branch Chief, Silver Spring, MD (Dec 2001 – Dec 2002)

- Supervised and coordinated activities associated with regulatory actions such as seizures, injunctions, civil money penalties, recalls and warning letters
- Supervised and coordinated reviews of premarket approval applications and establishment inspections and establishment inspection reports to ensure compliance with the Quality System Regulations

FDA/CDRH/ODE/Division of Cardiovascular and Respiratory Devices/Anesthesiology and Defibrillator Devices Group, Biomedical Engineer, Silver Spring, MD (May 1996 – Dec 2001)

- Served as a scientific reviewer specializing in ventilators, oxygen therapy devices, hyperbaric chambers, CPAP devices, anesthesia workstations, pulse oximeters, multi-parameter monitors, defibrillators and cardiac resynchronization therapy
- Participated in the highly competitive FDA Leadership Development program (April 2000 – December 2001) which included leadership training as well as details to: Health Canada, Minnesota District Office, Office of Science Coordination and Communication, Office of the Commissioner and CDRH, Office of Compliance

Naval Medical Research Institute, Biomedical Engineer, Bethesda MD (June 1989 – May 1996)

- Supported military research activities in areas of thermal stress, including assessing the pathophysiology of non-freezing cold injury as well as assessing cognitive decrements induced by cold weather operations

EDUCATION

M.B.E. Biomedical Engineering, The Catholic University of America, Washington, DC (2000)

B.B.E. Biomedical Engineering, The Catholic University of America, Washington, DC (1993)

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

MEMBERSHIPS

Regulatory Affairs Professional Society

SELECTED RELEVANT TRAINING

AAMI GMP Quality System Requirements and Industry Practice

AAMI Design Control Requirements and Industry Practice

AAMI Process Validation Requirements and Industry Practice AAMI CAPA Requirements and Industry Practice

Process Validation in Biotechnology Manufacturing Process Validation: Concepts and Applications

ASQ Introduction to Quality Engineering Food and Drug Law

Biostatistics

Maryland Emergency Medical Technician – B (expired)

PUBLICATIONS

- Book chapter on the regulation of hyperbaric chambers as medical devices. Hyperbaric Facility Safety: A Practical Approach 2nd Edition; 2020, edited by W.T. Workman and J. Steven Wood
- RM Kretzer, CL Foreman, JE Shuren (2010) Modernizing Device Regulation - Letter to the Editor, NEJM Jul 8;363(2):196-7; author reply 197.
- Book chapter on the regulation of hyperbaric chambers as medical devices. Hyperbaric Facility Safety: A Practical Approach; 1999, edited by W.T. Workman

SELECTED PRESENTATIONS/INVITED SPEAKER

- Instructor for RAPS European Workshop on 510(k) Basics and Working with FDA (10-11 October 2019)
- Testimony before the Subcommittee on Oversight and Investigations Committee on Energy and Commerce U.S. House of Representatives “Health Information Technologies: Administration Perspectives on Innovation and Regulation” March 21, 2013
- Presentation to the Institute of Medicine - Reviewing a 510(k), March 1, 2010
- Drug Information Association (DIA) CDRH Town Hall – June 2014
- MDMA FDA Forum: PMA/510(k) Workshop & FDA Reform – March 2014
 - Recent Trends in Device Review Process
 - Navigating Today's 510(k) Program
 - Clinical Trial Considerations
 - New World of DeNovo
 - PMA Review Considerations

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

- CDRH Update
- Complex Issues in Developing Medical Devices for Pediatric Patients Affected By Rare Diseases Workshop – Engineering Considerations for Pediatric Devices, January 2014
- Transcatheter Cardiovascular Therapeutics (TCT) FDA Town Hall, Oct 2013
- DIA 2013 49th Annual Meeting: Advancing Therapeutic Innovation and Regulatory Science – June 2013
- FDA/Xavier University Medcon Conference , April 2013
- MDMA's FDA Forum – PMA/510(k) Workshop, March 2013
 - An Overview of Current Device Regulation
 - Applying Lessons Learned – Illustrations
 - CDRH Update
 - Adapting to FDA's Newest Guidance Documents
 - Clinical Trials & IDE Decisions
- FDA/Xavier University Medcon Conference , May 2011
- IN3/Gray Sheet conference – 510(k) Program, October 2010
- RAPS Annual Conference 2010 – 510(k) Program, September 2010
- CDRH 510(k) Public Workshop – Use of Predicates, Feb 2010
- Organization of Regulatory and Clinical Associates, ODE Program Updates, Nov 2008
- USPHS Leadership Development Seminar – Strategic Thinking
- AdvaMed PMA Submissions Workshops – regular presenter
- AdvaMed Annual Meetings

ADDITIONAL INFORMATION

Adjunct Faculty

Biomedical Engineering, The Catholic University of America,

Washington, DC

Medical Device Design and Regulation, 2015- Present

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

Appendix B – Materials Considered

Pleadings

- Complaint, Surgical Instrument Service Co., Inc. v. Intuitive Surgical, Inc., No. 3:21-cv-03496-VC (ECF 1) (May 10, 2021)
- Consolidated Amended Class Action Complaint, In re: da Vinci Surgical Robot Antitrust Litigation, Lead Case No. 3:21-cv-03825-VC (ECF 52) (Sept. 9, 2021)
- Defendant Intuitive Surgical, Inc.'s Answer, Affirmative Defense and Counterclaims, Surgical Instrument Service Co., Inc. v. Intuitive Surgical, Inc., No. 3:21-cv-03496-VC (ECF 75) (Dec. 14, 2021)

Expert Reports

- Expert Report of Philip J. Phillips (Dec. 2, 2022) (*Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc.*)
- Expert Report of Dr. Robert D. Howe (Aug. 20, 2021) (*Restore Robotics LLC et al. v. Intuitive Surgical, Inc.*)
- Supplemental Expert Report of Dr. Robert D. Howe (Dec. 23, 2022) (*Restore Robotics LLC et al. v. Intuitive Surgical, Inc.*)
- Expert Report of Dr. Robert D. Howe (Dec. 2, 2022) (*Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc.*)
- Expert Report of Kurt Humphrey (Dec. 2, 2022) (*Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc.*)

Deposition Transcripts and Exhibits (*SIS* and *Larkin*)

- Deposition of Clifton Parker (Oct. 25, 2022) and Exhibits
- Deposition of Disha Peswani (Oct. 6, 2022) and Exhibits
- Deposition of Grant Duque (30(b)(1)) (Nov. 8, 2022) and Exhibits
- Deposition of Grant Duque (30(b)(6)) (Nov. 8, 2022) and Exhibits
- Deposition of Greg Posdal (30(b)(1)) (Nov. 1, 2022) and Exhibits
- Deposition of Greg Posdal (30(b)(6)) (Nov. 1, 2022) and Exhibits
- Deposition of Greta Bernier (Nov. 7, 2022) and Exhibits
- Deposition of John Sampson (Nov. 3, 2022) and Exhibits
- Deposition of Jose Gonzalez (30(b)(1)) (Oct. 17, 2022) and Exhibits
- Deposition of Jose Gonzalez (30(b)(6)) (Oct. 17, 2022) and Exhibits

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

- Deposition of Keith Johnson (30(b)(1)) (Oct. 27, 2022) and Exhibits
- Deposition of Keith Johnson (30(b)(6)) (Oct. 27, 2022) and Exhibits
- Deposition of Kevin May (Nov. 3, 2022) and Exhibits
- Deposition of Nicky Goodson (Oct. 27, 2022) and Exhibits
- Deposition of Ricardo Estape, M.D. (Oct. 22, 2022) and Exhibits
- Deposition of Rick Ferreira (Nov. 10, 2022) and Exhibits
- Deposition of Sharathchandra "Shark" Somayaji (Nov. 4, 2022) and Exhibits
- Deposition of Stan Hamilton (Nov. 4, 2022) and Exhibits

Deposition Transcripts and Exhibits (*Restore*)

- Deposition of Clifton Parker (30(b)(6)) (May 4, 2021) and Exhibits
- Deposition of Eugene Dickens, M.D. (May 27, 2021) and Exhibits
- Deposition of Kevin May (May 6, 2021) and Exhibits
- Deposition of Kevin May (June 8, 2021) and Exhibits
- Deposition of Rafal Chudzik (June 7, 2021) and Exhibits
- Deposition of Ricardo Ferreira (June 7, 2021) and Exhibits
- Deposition of Ronald Arkin (June 9, 2021) and Exhibits

Deposition Transcripts and Exhibits (*Rebotix*)

- Deposition of David Mixner (June 10, 2021) and Exhibits
- Deposition of Edward Harrich (May 24, 2021) and Exhibits
- Deposition of Stan Hamilton (Sept. 20, 2021) and Exhibits

Produced Documents

- | | | |
|-------------|-------------|-------------|
| • ACG000006 | • AHP000708 | • AHP002130 |
| • AHP000369 | • AHP000729 | • AHP002395 |
| • AHP000373 | • AHP000732 | • AHP002448 |
| • AHP000404 | • AHP000803 | • AHP002623 |
| • AHP000525 | • AHP000832 | • AHP002680 |
| • AHP000527 | • AHP000928 | • AHP003709 |
| • AHP000658 | • AHP000939 | • AHP005099 |
| • AHP000706 | • AHP002062 | • BPI000331 |

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

• Intuitive-00481165	• Intuitive-00692643	• REBOTIX077735
• Intuitive-00481167	• Intuitive-00693535	• REBOTIX077440
• Intuitive-00481176	• Intuitive-00694043	• REBOTIX131417
• Intuitive-00491017	• Intuitive-00705537	• REBOTIX131427
• Intuitive-00492705	• Intuitive-00705538	• REBOTIX131433
• Intuitive-00493504	• Intuitive-00705540	• REBOTIX131437
• Intuitive-00493612	• Intuitive-00705587	• REBOTIX131480
• Intuitive-00499468	• Intuitive-00705777	• REBOTIX131488
• Intuitive-00515501	• Intuitive-00705778	• REBOTIX131493
• Intuitive-00552632	• Intuitive-00706011	• REBOTIX131501
• Intuitive-00552682	• Intuitive-00706083	• REBOTIX131514
• Intuitive-00552744	• Intuitive-00861667	• REBOTIX146948
• Intuitive-00552745	• Intuitive-01019873	• REBOTIX155894
• Intuitive-00552993	• Intuitive-02054168	• REBOTIX169168
• Intuitive-00691203	• Intuitive-02067581	• REBOTIX169588
• Intuitive-00691613	• Intuitive-02067582	• REBOTIX169683
• Intuitive-00691658	• Intuitive-02067588	• REBOTIX169926
• Intuitive-00691660	• Intuitive-02068246	• REBOTIX169947
• Intuitive-00691710	• REBOTIX077238	• REBOTIX170053
• Intuitive-00691802	• REBOTIX077440	• REBOTIX170421
• Intuitive-00691837	• REBOTIX077446	• REBOTIX171030
• Intuitive-00691847	• REBOTIX077536	• REBOTIX171058
• Intuitive-00691857	• REBOTIX077545	• REBOTIX171073
• Intuitive-00692185	• REBOTIX077549	• REBOTIX171076
• Intuitive-00692310	• REBOTIX077597	• REBOTIX175326
• Intuitive-00692314	• REBOTIX077601	• REBOTIX175327
• Intuitive-00692321	• REBOTIX077611	• REBOTIX175417
• Intuitive-00692433	• REBOTIX077617	• REBOTIX175419
• Intuitive-00692451	• REBOTIX077671	• REBOTIX175468
• Intuitive-00692611	• REBOTIX077729	• REBOTIX175710

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

• Restore-00001248	• Restore-00086586	• Restore-00091253
• Restore-00007128	• Restore-00086681	• Restore-00091261
• Restore-00009030	• Restore-00086828	• Restore-00091314
• Restore-00010132	• Restore-00086846	• Restore-00091328
• Restore-00034134	• Restore-00086859	• Restore-00091362
• Restore-00055573	• Restore-00086866	• Restore-00091363
• Restore-00055935	• Restore-00086873	• Restore-00091364
• Restore-00055937	• Restore-00086891	• Restore-00091434
• Restore-00060739	• Restore-00086907	• Restore-00091459
• Restore-00060741	• Restore-00087401	• Restore-00091468
• Restore-00062443	• Restore-00089490	• Restore-00094345
• Restore-00062688	• Restore-00089718	• Restore-00094450
• Restore-00063245	• Restore-00089994	• Restore-00094476
• Restore-00063246	• Restore-00090004	• Restore-00094486
• Restore-00063284	• Restore-00090030	• Restore-00094488
• Restore-00063474	• Restore-00090136	• Restore-00094491
• Restore-00063595	• Restore-00090149	• Restore-00094517
• Restore-00063598	• Restore-00090617	• Restore-00094561
• Restore-00064367	• Restore-00091087	• Restore-00094567
• Restore-00064369	• Restore-00091138	• Restore-00094588
• Restore-00064384	• Restore-00091141	• Restore-00094610
• Restore-00064401	• Restore-00091153	• Restore-00094721
• Restore-00064403	• Restore-00091157	• Restore-00094779
• Restore-00064407	• Restore-00091171	• Restore-00094987
• Restore-00064566	• Restore-00091178	• Restore-00095021
• Restore-00086093	• Restore-00091185	• Restore-00095027
• Restore-00086121	• Restore-00091193	• Restore-00095069
• Restore-00086179	• Restore-00091202	• Restore-00095075
• Restore-00086192	• Restore-00091218	• Restore-00095127
• Restore-00086401	• Restore-00091222	• Restore-00095226

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

- Restore-00095250
- Restore-00095266
- Restore-00095284
- Restore-00095300
- Restore-00095403
- Restore-00095481
- Restore-00095491
- Restore-00095533
- Restore-00095583
- Restore-00095585
- Restore-00095608
- Restore-00095616
- Restore-00095678
- Restore-00095704
- Restore-00096294
- Restore-00096301
- Restore-00098415
- Restore-00099136
- Restore-00099137
- Restore-00099139
- Restore-00102436
- Restore-00102495
- Restore-00102835
- Restore-00103167
- Restore-00103331
- Restore-00104982
- Restore-00104984
- Restore-00105001
- Restore-00105466
- Restore-00106446
- Restore-00107476
- Restore-00107513
- Restore-00108307
- Restore-00109056
- Restore-00109203
- Restore-00112001
- Restore-00112022
- Restore-00112595
- Restore-00112674
- Restore-00113239
- Restore-00114323
- Restore-00117633
- Restore-00117692
- Restore-00122811
- Restore-00131763
- Restore-00132592
- Restore-00134924
- SIS357813
- VMC-00018032

Publications

- “Device Ownership Should Not Be Criterion for Regulation of Reprocessors,” The Gray Sheet, Vol. 24, No. 27 (July 6, 1998)
- FDA, “Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended – Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices” (May 1, 2006), available at <https://www.fda.gov/media/71187/download> (last accessed Jan. 17, 2023)
- FDA, “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices - Draft Guidance for Industry and Food and Drug Administration Staff” (June 14, 2013), available at <https://www.regulations.gov/document/FDA-2013-D-0616-0002> (last accessed Jan. 17, 2023)
- FDA, Content of Premarket Submissions for Management of Cybersecurity in Medical Devices - Draft Guidance for Industry and Food and Drug Administration Staff” (Oct. 2, 2014), available at <https://www.fda.gov/media/86174/download> (last accessed Jan. 17, 2023)

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

- FDA, “CPG § 300.500 (Reprocessing of Single Use Devices)”, available at: <https://www.fda.gov/media/71769/download> (last accessed Jan. 17, 2023)
- FDA, “Deciding When to Submit a 510(k) for a Change to an Existing Device” (Oct. 25, 2017) (originally issued Jan. 10, 1997), available at <https://www.fda.gov/media/99812/download> (last accessed Jan. 17, 2023)
- FDA, “Deciding When to Submit a 510(k) for a Software Change to an Existing Device” (Oct. 25, 2017), available at <https://www.fda.gov/media/99785/download> (last accessed Jan. 17, 2023)
- FDA, “Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications” (Aug. 30, 2019) (originally issued Mar. 28, 2012), available at <https://www.fda.gov/media/99769/download> (last accessed Jan. 17, 2023)
- FDA, “General Principles of Software Validation; Final Guidance for Industry and FDA Staff” (Jan. 11, 2002), available at <https://www.fda.gov/media/73141/download> (last accessed Jan. 17, 2023)
- FDA, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” (May 11, 2005), available at <https://www.fda.gov/media/73065/download> (last accessed Jan. 17, 2023)
- FDA, “Guidance for Industry, Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software” (Jan. 14, 2005), available at <https://www.fda.gov/media/72154/download> (last accessed Jan. 17, 2023)
- FDA, “Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices” (Sept. 9, 1999), available at <https://www.inec.com/PDF/otssguid> (last accessed Jan. 17, 2023)
- FDA, K210478 510(k) Summary, available at: https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210478 (last accessed Jan. 17, 2023)
- FDA, “Format for Traditional and Abbreviated 510(k)s” (Sept. 13, 2019) (originally issued Aug. 12, 2005), available at <https://www.fda.gov/media/130647/download> (last accessed Jan. 17, 2023)
- FDA, “Medical Device Classification Product Codes” (Apr. 11, 2013), available at <https://www.fda.gov/media/82781/download> (last accessed Jan. 17, 2023)
- FDA, “Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices” (Sept. 25, 2006) (originally issued June 1, 2004), available at <https://www.fda.gov/media/71482/download> (last accessed Jan. 17, 2023)
- FDA, “Off-The-Shelf Software Use in Medical Devices” (Sept. 27, 2019), available at <https://www.fda.gov/media/71794/download> (last accessed Jan. 17, 2023)

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

- FDA, “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance” (Mar. 17, 2015), available at <https://www.fda.gov/media/80265/download> (last accessed Jan. 17, 2023)
- FDA, “The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]” (July 28, 2014), available at <https://www.fda.gov/media/82395/download> (last accessed Jan. 17, 2023)
- FDA, “White Paper: Evaluating Whether Activities are Servicing or Remanufacturing” (December 2018), available at <https://www.fda.gov/media/117238/download> (last accessed Jan. 17, 2023)
- FDA Report on the Quality, Safety and Effectiveness of Servicing of Medical Devices (May 2018), available at <https://www.fda.gov/media/113431/download> (last accessed Jan. 17, 2023)

Other Documents

- Code of Federal Regulations
 - 21 CFR § 10
 - 21 CFR § 801
 - 21 CFR § 803
 - 21 CFR § 806
 - 21 CFR § 807
 - 21 CFR § 814
 - 21 CFR § 820
 - 21 CFR § 821
 - 21 CFR § 860
 - 21 CFR § 862
 - 21 CFR § 864
 - 21 CFR § 876
 - 21 CFR § 878
- Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*)
- Federal Register

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

- 58 Fed. Reg. 61952 (Nov. 23, 1993)
- 61 Fed. Reg. 52602 (Oct. 7, 1996)
- 62 Fed. Reg. 8961 (Feb. 27, 1997)
- 63 Fed. Reg. 67076 (Dec. 4, 1998)
- H.R. Rept. 94-853, at 15 (Feb. 29, 1976)
- Letter from Counsel to the Association of Medical Device Reprocessors to FDA (Mar. 23, 1998)
- Letter from Johnson & Johnson to FDA (Mar. 23, 1998)
- Letter from Ronald E. Eames, President and Managing Director, Medical Devices Services, Inc. to FDA (Mar. 21, 2000)
- Medical Device User Fee and Modernization Act of 2002, PL 107-250, October 26, 2002, 116 Stat 1588.
- Plaintiff Rebotix Repair, LLC's Disclosure Pursuant to Fed. R. Civ. P. 26(a)(2)(c) (Stan Hamilton (Aug. 30, 2021) (*Rebotix Repair LLC v. Intuitive Surgical, Inc.*)
- Prepared Testimony of Vern Feltner, President of Alliance Medical Corporation, on behalf of the Association of Medical Device Reprocessors (June 27, 2000)

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

Appendix C - QSM and NAY Premarket Submissions

Device Name	Applicant	510(K) Number	Decision Date
<u>Da Vinci X Surgical System (Is4200), Da Vinci Xi Surgical System (Is4000)</u>	Intuitive Surgical, Inc	<u>K223080</u>	11/22/2022
<u>Da Vinci Firefly Imaging System</u>	Intuitive Surgical Inc.	<u>K222827</u>	10/20/2022
<u>8mm Monopolar Curved Scissors</u>	Iconocare Health	<u>K210478</u>	09/30/2022
<u>Da Vinci X/Xi (Is4200/Is4000) 8mm Reusable Instruments</u>	Intuitive Surgical, Inc.	<u>K214095</u>	08/15/2022
<u>Senhance Surgical System</u>	Asensus Surgical, Inc.	<u>K220889</u>	05/27/2022
<u>Da Vinci Fluorescence Imaging Vision System, Da Vinci Firefly Imaging System</u>	Intuitive Surgical, Inc.	<u>K213710</u>	02/17/2022
<u>8mm Monopolar Curved Scissors</u>	Intuitive Surgical, Inc.	<u>K220023</u>	01/31/2022
<u>8 Mm Sureform 30 Curved-Tip Stapler, 8 Mm Sureform 30 Stapler, Sureform 30 Reloads</u>	Intuitive Surgical, Inc.	<u>K211997</u>	12/10/2021
<u>Da Vinci Sp Firefly Imaging System</u>	Intuitive Surgical, Inc.	<u>K212101</u>	11/23/2021
<u>Da Vinci Sp Surgical System</u>	Intuitive Surgical, Inc.	<u>K212747</u>	09/29/2021
<u>Handx</u>	Human Xtensions Ltd.	<u>K212214</u>	09/13/2021
<u>Senhance Surgical System</u>	Asensus Surgical, Inc.	<u>K212054</u>	08/30/2021
<u>Da Vinci Xi Surgical System (Is4000), Da Vinci X Surgical System (Is4200)</u>	Intuitive Surgical, Inc.	<u>K211784</u>	08/06/2021
<u>Senhance Surgical System</u>	Asensus Surgical, Inc.	<u>K211325</u>	07/27/2021
<u>Da Vinci Sp Surgical System (Sp1098)</u>	Intuitive Surgical, Inc.	<u>K211316</u>	07/23/2021
<u>Stitchkit</u>	Origami Surgical Inc .	<u>K211792</u>	07/16/2021
<u>Da Vinci Sp Surgical System (Sp1098)</u>	Intuitive Surgical, Inc.	<u>K211595</u>	06/23/2021
<u>Da Vinci Fluorescence Imaging Vision System, Da Vinci Firefly Imaging System</u>	Intuitive Surgical, Inc.	<u>K210918</u>	04/26/2021
<u>Senhance Surgical System</u>	TransEnterix, Inc.	<u>K202166</u>	03/02/2021
<u>Stitchkit Combo</u>	Origami Surgical	<u>K202950</u>	02/23/2021
<u>Da Vinci S/Si (Is2000/Is3000) 5mm And 8mm Reusable Instruments, Da Vinci Xi/X (Is4000/Is4200) 8mm Reusable Instruments</u>	Intuitive Surgical, Inc.	<u>K203632</u>	02/10/2021
<u>Soloasisst II, Voice Control</u>	AKTORMed GmbH	<u>K200473</u>	12/22/2020
<u>Da Vinci Sp Surgical System</u>	Intuitive Surgical, Inc.	<u>K202968</u>	12/22/2020

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

Device Name	Applicant	510(K) Number	Decision Date
<u>Da Vinci Xi Surgical System (Is4000), Da Vinci X Surgical System (Is4200)</u>	Intuitive Surgical, Inc.	<u>K202834</u>	12/10/2020
<u>Da Vinci Sp Surgical System, Model Sp1098, Endowrist Sp Instruments, And Accessories</u>	Intuitive Surgical, Inc.	<u>K202571</u>	11/12/2020
<u>Da Vinci Sp Surgical System</u>	Intuitive Surgical Inc.	<u>K192717</u>	09/28/2020
<u>Da Vinci Xi Surgical System, Da Vinci X Surgical System</u>	Intuitive Surgical	<u>K192803</u>	04/29/2020
<u>Da Vinci X And Xi Surgical System</u>	Intuitive Surgical, Inc	<u>K183086</u>	03/31/2020
<u>Senhance Surgical System</u>	TransEnterix, Inc.	<u>K200049</u>	03/09/2020
<u>Da Vinci Xi Surgical System, Da Vinci X Surgical System</u>	Intuitive Surgical	<u>K191529</u>	02/06/2020
<u>Senhance Surgical System</u>	TransEnterix, Inc.	<u>K192877</u>	11/22/2019
<u>E-100 Electrosurgical Generator, Synchro Seal</u>	Intuitive Surgical, Inc.	<u>K191280</u>	11/14/2019
<u>Da Vinci X/Xi 8mm Endoscope Plus, 0, Da Vinci X/Xi 8mm Endoscope Plus, 30</u>	Intuitive Surgical	<u>K191736</u>	07/26/2019
<u>Stitchkit</u>	Origami Surgical	<u>K191317</u>	07/12/2019
<u>Sureform 45 Curved Tip, Sureform 45 Gray Reload</u>	Intuitive Surgical, Inc.	<u>K190999</u>	07/12/2019
<u>Senhance Surgical System</u>	TransEnterix Inc.	<u>K191482</u>	07/11/2019
<u>Da Vinci Sp Surgical System, Endowrist Sp Instruments, And Accessories</u>	Intuitive Surgical, Inc.	<u>K182371</u>	03/14/2019
<u>Sureform 45, Sureform 45 Reloads</u>	Intuitive Surgical	<u>K183224</u>	01/18/2019
<u>Senhance Ultrasonic System</u>	TransEnterix, Inc.	<u>K182421</u>	01/11/2019
<u>Intuitive Surgical Vessel Sealer Extend</u>	Intuitive Surgical, Inc.	<u>K183107</u>	12/11/2018
<u>Senhance Surgical System</u>	TransEnterix, Inc.	<u>K183098</u>	12/06/2018
<u>Da Vinci Xi Surgical System, Da Vinci X Surgical System</u>	Intuitive Surgical, Inc	<u>K182140</u>	10/24/2018
<u>Senhance Surgical System</u>	TransEnterix, Inc.	<u>K181517</u>	10/09/2018
<u>Soloassist li</u>	AKTORmed GmbH	<u>K171947</u>	09/21/2018
<u>Endowrist Mercury Bipolar Grasper</u>	Intuitive Surgical, Inc.	<u>K180351</u>	08/07/2018
<u>Da Vinci Xi Surgical System, Da Vinci X Surgical System</u>	Intuitive Surgical, Inc.	<u>K173585</u>	07/19/2018
<u>Sureform 60 And Sureform 60 Reloads</u>	Intuitive Surgical	<u>K173721</u>	07/05/2018
<u>Da Vinci Sp Surgical System, Endowrist Sp Instruments, And Accessories</u>	Intuitive Surgical, Inc.	<u>K173906</u>	05/31/2018
<u>Endowrist 5mm Thoracic Grasper</u>	Intuitive Surgical, Inc.	<u>K173415</u>	05/31/2018

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

Device Name	Applicant	510(K) Number	Decision Date
<u>Transenterix Senhance Surgical System</u>	TransEnterix, Inc.	<u>K180163</u>	05/25/2018
<u>Stitchkit V-Loc 90, Stitchkit V-Loc 180, Stitchkit Quill Pdo</u>	Origami Surgical LLC	<u>K173874</u>	05/04/2018
<u>Intuitive Surgical Endowrist Vessel Sealer Extend</u>	Intuitive Surgical, Inc.	<u>K173337</u>	04/26/2018
<u>Da Vinci Xi Surgical System, Da Vinci X Surgical System</u>	Intuitive Surgical, Inc	<u>K173842</u>	04/23/2018
<u>8mm Monopolar Curved Scissors</u>	Intuitive Surgical, Inc	<u>K180033</u>	04/06/2018
<u>Hx Device</u>	Human Extension Ltd.	<u>K173919</u>	03/20/2018
<u>Da Vinci Xi Surgical System; Da Vinci X Surgical System</u>	Intuitive Surgical, Inc.	<u>K172643</u>	01/31/2018
<u>Senhance Surgical Robotic System</u>	TransEnterix, Inc.	<u>K171120</u>	10/13/2017
<u>Da Vinci S/Si Endoscopes, Da Vinci Xi Endoscopes</u>	Intuitive Surgical, Inc.	<u>K170641</u>	09/21/2017
<u>Is4000 Stapler 45 Instrument And Its Reusable Accessories, Is4000 Endowrist Stapler 30 Instrument, Is3000 Stapler 45 Instrument And Its Reusable Accessories</u>	Intuitive Surgical, Inc.	<u>K170879</u>	09/21/2017
<u>Da Vinci Xi Surgical System</u>	Intuitive Surgical, Inc	<u>K171632</u>	09/19/2017
<u>Da Vinci Si Single-Site Instruments And Accessories, Da Vinci Xi Single-Site Instruments And Accessories</u>	Intuitive Surgical, Inc.	<u>K170875</u>	09/12/2017
<u>Da Vinci S/Si Endowrist Instruments And Accessories, Harmonic Ace Curved Shears (5mm & 8mm)</u>	Intuitive Surgical, Inc.	<u>K170644</u>	09/11/2017
<u>Da Vinci Xi Endowrist Instruments And Accessories</u>	Intuitive Surgical, Inc.	<u>K170645</u>	09/11/2017
<u>Da Vinci Xi Surgical System, Da Vinci Si Surgical System, Da Vinci X Surgical System</u>	Intuitive Surgical, Inc	<u>K171699</u>	07/28/2017
<u>Da Vinci Xi 8mm Endoscope, 0 Degree, Da Vinci Xi 8mm Endoscope, 30 Degree</u>	Intuitive Surgical, Inc.	<u>K171426</u>	06/13/2017
<u>Da Vinci Xi Surgical System</u>	Intuitive Surgical, Inc	<u>K170713</u>	06/13/2017
<u>Endowrist Stapler 45 System And Stapler 45 Reloads</u>	Intuitive Surgical, Inc.	<u>K171388</u>	05/31/2017
<u>Da Vinci X Surgical System</u>	Intuitive Surgical, Inc.	<u>K171294</u>	05/26/2017
<u>Endowrist Vessel Sealer, 8 Mm Harmonic Ace Curved Shears, Da Vinci Single-Site Instruments And Accessories</u>	Intuitive Surgical, Inc.	<u>K170865</u>	04/21/2017
<u>Endowrist Stapler 45 Instrument, Endowrist Stapler 45 Reloads, Endowrist Stapler 30 Instrument, Endowrist Stapler 30 Reloads</u>	Intuitive Surgical, Inc.	<u>K170508</u>	03/10/2017
<u>Endowrist Suction Irrigator</u>	Intuitive Surgical, Inc.	<u>K162973</u>	02/06/2017
<u>Da Vinci Xi Surgical System</u>	Intuitive Surgical, Inc.	<u>K161178</u>	01/19/2017

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

Device Name	Applicant	510(K) Number	Decision Date
<u>Da Vinci Xi 12 – 8 Mm Reducer</u>	Intuitive Surgical, Inc.	<u>K162411</u>	09/21/2016
<u>Da Vinci Xi Surgical System</u>	INTUITIVE SURGICAL, INC.	<u>K153276</u>	08/07/2016
<u>Da Vinci Xi Surgical System</u>	Intuitive Surgical, Inc.	<u>K161271</u>	07/11/2016
<u>Da Vinci Xi Surgical System</u>	INTUITIVE SURGICAL	<u>K152892</u>	04/29/2016
<u>Da Vinci Surgical System, Model Is4000</u>	INTUITIVE SURGICAL, INC.	<u>K152578</u>	03/30/2016
<u>Da Vinci Single-Site Instrument And Accessories</u>	INTUITIVE SURGICAL, INC.	<u>K152448</u>	03/09/2016
<u>Is4000 Stapler 30 Instrument And Stapler 30 Reloads</u>	INTUITIVE SURGICAL, INC.	<u>K152421</u>	03/04/2016
<u>Da Vinci Xi Surgical System</u>	Intuitive Surgical, Inc.	<u>K151794</u>	01/15/2016
<u>Is4000 Da Vinci Endowrist Instruments</u>	INTUITIVE SURGICAL, INC.	<u>K150284</u>	05/15/2015
<u>Is4000 Small Clip Applier, Is4000 Long Bipolar Forceps</u>	INTUITIVE SURGICAL, INC.	<u>K150837</u>	04/29/2015
<u>Is4000 8mm Harmonic Ace Curved Shears</u>	INTUITIVE SURGICAL, INC.	<u>K143132</u>	04/02/2015
<u>Stitchkit</u>	ORIGAMI SURGICAL LLC	<u>K142639</u>	12/16/2014
<u>12 Mm Endoscopes And Accessories</u>	INTUITIVE SURGICAL, INC.	<u>K142683</u>	12/10/2014
<u>12 Mm & Stapler Bladeless Obturators</u>	INTUITIVE SURGICAL, INC.	<u>K143217</u>	12/03/2014
<u>Single-Site Wristed Needle Driver</u>	INTUITIVE SURGICAL	<u>K141075</u>	09/26/2014
<u>Da Vinci Surgical System</u>	INTUITIVE SURGICAL, INC.	<u>K123329</u>	09/17/2014
<u>Da Vinci Firefly Imaging System</u>	INTUITIVE SURGICAL, INC.	<u>K141077</u>	08/12/2014
<u>Endowrist Stapler 45 And Stapler 45 Reloads</u>	INTUITIVE SURGICAL, INC.	<u>K140553</u>	07/25/2014
<u>Endowrist Vessel Sealer</u>	INTUITIVE SURGICAL, INC.	<u>K140189</u>	06/05/2014
<u>Single-Site Port</u>	INTUITIVE SURGICAL, INC.	<u>K133203</u>	05/09/2014
<u>Da Vinci Sp Surgical System, Endowrist Sp Instruments, And Accessories</u>	INTUITIVE SURGICAL, INC.	<u>K131962</u>	04/17/2014
<u>Da Vinci Surgical System, Endowrist Instruments And Accessories</u>	INTUITIVE SURGICAL, INC.	<u>K131861</u>	03/28/2014
<u>Stitchkit</u>	ORIGAMI SURGICAL LLC	<u>K123811</u>	09/05/2013
<u>Endowrist One Vessel Sealer</u>	INTUITIVE SURGICAL, INC.	<u>K130266</u>	08/29/2013
<u>Da Vinci Single-Site Instruments And Accessories</u>	INTUITIVE SURGICAL, INC.	<u>K122532</u>	07/30/2013
<u>Da Vinci Single-Site Permanent Cautery Hook</u>	INTUITIVE SURGICAL, INC.	<u>K130726</u>	06/07/2013

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

Device Name	Applicant	510(K) Number	Decision Date
<u>Connect For Da Vinci Surgical System(S)</u>	INTUITIVE SURGICAL, INC.	<u>K123840</u>	02/14/2013
<u>Intuitive Surgical Da Vinci Si Surgical System Smartpedals</u>	INTUITIVE SURGICAL, INC.	<u>K123463</u>	12/03/2012
<u>Intuitive Surgical Onsite For Da Vinci Surgical Systems</u>	INTUITIVE SURGICAL, INC.	<u>K121921</u>	10/25/2012
<u>Endowrist Stapler System</u>	INTUITIVE SURGICAL, INC.	<u>K113706</u>	10/17/2012
<u>Single-Site Medium-Large Clip Applier, Single-Site Cadiere Grasper, Single-Site Fundus Grasper, Single-Site Crocodile</u>	INTUITIVE SURGICAL, INC.	<u>K120215</u>	04/30/2012
<u>Endowrist One Vessel Sealer</u>	INTUITIVE SURGICAL, INC.	<u>K110639</u>	12/28/2011
<u>Intuitive Surgical Da Vinci Single Site Instruments And Accessories</u>	INTUITIVE SURGICAL, INC.	<u>K112208</u>	12/08/2011
<u>Monopolar Curved Scissors Tip Cover Accessory</u>	INTUITIVE SURGICAL, INC.	<u>K112263</u>	10/07/2011
<u>5mm/8mm Harmonic Ace(Tm) Curved Shears, Disposable Harmonic Ace(Tm) Insert, Disposable Harmonic(Tm) Curved Shears Insert</u>	INTUITIVE SURGICAL, INC.	<u>K112584</u>	09/29/2011
<u>Endowrist One Suction/Irrigator</u>	INTUITIVE SURGICAL, INC.	<u>K110451</u>	08/26/2011
<u>Intuitive Surgical Da Vinci S Surgical System With Da Vinci Connect & Da Vinci Onsite, Model Is2000</u>	INTUITIVE SURGICAL, INC.	<u>K101581</u>	04/08/2011
<u>5mm Flared Cannula Model 420262, 8mm Flared Cannula Model 420319</u>	INTUITIVE SURGICAL, INC.	<u>K101743</u>	02/04/2011
<u>Da Vinci Fluorescence Imaging Vision System, Model Ff 100</u>	INTUITIVE SURGICAL, INC.	<u>K101077</u>	02/04/2011
<u>5 Mm Harmonic Ace Instrument (Used With Da Vinci Is1200 & Is2000/Is3000 System)</u>	INTUITIVE SURGICAL, INC.	<u>K093217</u>	01/21/2010
<u>Intuitive Surgical Endoscopic Instrument Control Systems, Models Is1200, Is2000 And Is3000</u>	INTUITIVE SURGICAL, INC.	<u>K090993</u>	12/16/2009
<u>Intuitive Surgical Endowrist One Hot Shears Instrument</u>	INTUITIVE SURGICAL, INC.	<u>K082497</u>	05/07/2009
<u>Intuitive Surgical Da Vinci Si Surgical System: Model Is3000</u>	INTUITIVE SURGICAL, INC.	<u>K081137</u>	02/18/2009
<u>Intuitive Surgical Da Vinci S Surgical System, Model Is2000, With Da Vinci Connect And Onsite</u>	INTUITIVE SURGICAL, INC.	<u>K081207</u>	12/19/2008
<u>Intuitive Surgical Da Vinci Endoscopic Instruments And Control System And Endowrist Stabilizer</u>	INTUITIVE SURGICAL, INC.	<u>K080291</u>	03/19/2008
<u>Intuitive Surgical Da Vinci Surgical System And Endoscopic Instruments And Endowrist Cardiac Probe Grasper</u>	INTUITIVE SURGICAL, INC.	<u>K070947</u>	02/14/2008
<u>Intuitive Surgical Da Vinci And Da Vinci S Surgical System And Endoscopic Instruments And Endowrist Introducer</u>	INTUITIVE SURGICAL, INC.	<u>K072627</u>	02/07/2008

HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

Device Name	Applicant	510(K) Number	Decision Date
<u>Da Vinci S Surgical System-V1.1, Model Is2000</u>	INTUITIVE SURGICAL, INC.	<u>K063220</u>	12/01/2006
<u>Intuitive Surgical Endowrist Pk Dissecting Forceps, Models 400214 & 420214</u>	INTUITIVE SURGICAL, INC.	<u>K061260</u>	05/18/2006
<u>Intuitive Surgical Endowrist Stabilizer, Model 420182</u>	INTUITIVE SURGICAL, INC.	<u>K060391</u>	04/10/2006
<u>Modification To Intuitive Surgical Da Vinci Surgical System And Endoscopic Instruments</u>	INTUITIVE SURGICAL, INC.	<u>K050802</u>	06/29/2005
<u>Intuitive Surgical Da Vinci Surgical System, Model Is2000</u>	INTUITIVE SURGICAL, INC.	<u>K050369</u>	04/29/2005
<u>Modification To Intuitive Surgical Da Vinci Surgical System And Endoscopic Instruments</u>	INTUITIVE SURGICAL, INC.	<u>K043288</u>	03/03/2005
<u>Intuitive Surgical Monopolar Curved Scissors, Model 400179; Tip Cover Accessory, Model 400180</u>	INTUITIVE SURGICAL, INC.	<u>K050005</u>	01/25/2005
<u>Intuitive Surgical Da Vinci Surgical System And Endoscopic Instruments, Models Is1200 & Is1000</u>	INTUITIVE SURGICAL, INC.	<u>K043153</u>	12/15/2004
<u>Intuitive Surgical Harmonic Curved Shears Instrument</u>	INTUITIVE SURGICAL, INC.	<u>K042855</u>	11/12/2004
<u>Intuitive Surgical Da Vinci Endoscopic Instrument Control System And Endoscopic Instruments</u>	INTUITIVE SURGICAL, INC.	<u>K040237</u>	07/07/2004
<u>Intuitive Surgical Endopass Endoscopic Delivery Instrument, Model P/N 400170</u>	INTUITIVE SURGICAL, INC.	<u>K040948</u>	05/05/2004
<u>Bipolar Grasper And Bipolar Scissors For The Zeus Microwrist Surgical System</u>	COMPUTER MOTION, INC.	<u>K030578</u>	06/24/2003
<u>Intuitive Surgical Endoscopic Instrument Control System & Endoscopic Instruments, Model Da Vinci Isi 1000/1200</u>	INTUITIVE SURGICAL, INC.	<u>K022574</u>	11/12/2002
<u>Zeus Microwrist Robotic Surgical System And Accessories</u>	COMPUTER MOTION, INC.	<u>K021152</u>	09/24/2002
<u>Intuitive Surgical Da Vinci Surgical System, Model Is1000</u>	INTUITIVE SURGICAL, INC.	<u>K021036</u>	06/26/2002
<u>Intuitive Surgical Bipolar Forceps</u>	INTUITIVE SURGICAL, INC.	<u>K012833</u>	11/16/2001
<u>Intuitive Surgical Ultrasonic Shears</u>	INTUITIVE SURGICAL, INC.	<u>K011281</u>	07/24/2001
<u>Intuitive Surgical Da Vinci Surgical System, Model Isi 1000</u>	INTUITIVE SURGICAL, INC.	<u>K011002</u>	05/30/2001
<u>Intuitive Surgical Da Vinci Endoscopic Control System</u>	INTUITIVE SURGICAL, INC.	<u>K002489</u>	03/02/2001
<u>Intuitive Surgical Endoscopic Instruments, Intuitive Surgical Endoscopic Instrument Control System</u>	INTUITIVE SURGICAL, INC.	<u>K990144</u>	07/11/2000

Exhibit 4

ATTACHMENT 29

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA**

IN RE: DA VINCI SURGICAL ROBOT
ANTITRUST LITIGATION

Lead Case No.: 3:21-cv-03825-VC

THIS DOCUMENT RELATES TO:
ALL ACTIONS

Expert Report of Dr. Robert D. Howe
OUTSIDE COUNSEL ONLY—SUBJECT TO PROTECTIVE ORDER

January 18, 2023

Table of Contents

I.	Qualifications.....	1
II.	Assignment	2
III.	Summary of Opinions	6
IV.	The Intuitive EndoWrist Instrument and the Interceptor	10
	A. Overview of Intuitive S/Si EndoWrist Instruments.....	10
	B. Differences Between Intuitive EndoWrist Instruments and Traditional Laparoscopic Instruments	13
	C. Overview of Interceptor Technology.....	22
V.	Intuitive’s Design Control, Risk Management, and Testing Processes	25
	A. Intuitive’s Design Control and Risk Management Processes	25
	1. Design Control	26
	2. Risk Management	27
	3. Design Verification and Validation	30
	B. Intuitive Designs and Tests Its EndoWrist Instruments to Reliably and Safely Perform Over a Set Number of “Lives”	32
	C. As EndoWrist Instruments Are Used in a Hospital Setting to Perform Surgical Procedures, They Experience Wear and Tear that Ultimately Leads to Instrument Failure.	39
VI.	Limitations and Risks of the Interceptor and “EndoWrist Service Procedure”	43
	A. Risks Associated with the Rebotix “EndoWrist Service Procedure”	44
	B. Rebotix’s Inadequate Risk Management and Life Testing.....	52
	1. Rebotix’s Risk Management.....	52
	2. Rebotix’s Life Testing	59
	C. Rebotix’s Summary of Quality and Reliability Measures and Technical File Review Do Not Support Any Safety and Reliability Claims.	65

VII.	Intuitive’s Efforts to Create a Refurbishment Program Do Not Prove the Safety or Reliability of EndoWrists Reset by Third Parties.....	69
VIII.	The FDA’s Recent Clearance of the Iconocare Process Does Not Prove the Safety and Reliability of Other Resetting Processes.....	70
A.	The Iconocare Remanufacturing Process.....	70
B.	The Rebotix Process and Iconocare Process Are Materially Different.	71
C.	The Rebotix Process and Iconocare Process are Supported by Materially Different Risk Management and Life Testing Data.....	76
D.	Significantly Greater Safety Risks Are Created by Resetting an EndoWrist Usage Counter Multiple Times.....	80
IX.	Comparison of Intuitive’s da Vinci System Service, Maintenance, and Repair Procedures with Restore’s da Vinci System “Service” Offering.....	81
A.	Intuitive’s da Vinci System Service, Maintenance, and Repair Procedures	82
1.	Preventative Maintenance	83
2.	Repair/replacement of damaged parts.....	91
B.	Restore’s da Vinci System “Service” Offering.....	92
1.	Overview of Restore’s da Vinci “Service”	92
2.	Restore’s Technological Limitations Prevent It from Providing Adequate Preventative Maintenance or Repair of da Vinci Systems	96

I. Qualifications

1. I received a Ph.D. in Mechanical Engineering from Stanford University in 1990, a Masters in Mechanical Engineering from Stanford University in 1985, and a Bachelor degree in Physics from Reed College in 1979. Prior to attending graduate school I worked in Silicon Valley as an electronics engineer, designing analog and digital electronics. Since receiving my doctorate, I have devoted my professional career to the research, design, development, study, and teaching of numerous aspects of mechanical and bioengineering.

2. I am currently the Abbott and James Lawrence Professor of Engineering at the Harvard Paulson School of Engineering and Applied Sciences. I serve as the founding co-chair of the Harvard MS/MBA degree program, a joint effort of Harvard's engineering and business schools aimed at training leaders in commercialization of technology. I am also a core faculty member of the Harvard-MIT Division of Health Sciences and Technology, a premier biomedical graduate training program. In 1990, I founded the Harvard BioRobotics Laboratory, which investigates the roles of sensing and mechanical design and motor control in both humans and robots. I have taught numerous courses at Harvard ranging from entry-level mechanical engineering courses to graduate-level robotics and bioengineering seminars. In 2007, I was elected Fellow of the American Institute for Medical and Biological Engineering, and in 2012, I was elected Fellow of the Institute of Electrical and Electronic Engineers. I have held visiting and adjunct scientist or professor positions at the Massachusetts Institute of Technology, Stanford University, Tufts University, and several foreign institutes and universities.

3. I am a named inventor on nine patents involving robotic and medical device technology and am the author or co-author of over 200 peer-reviewed technical publications.

4. I provided expert testimony in *Rebotix Repair LLC v. Intuitive Surgical, Inc.* and *Restore Robotics LLC and Restore Robotics Repair v. Intuitive Surgical, Inc.* In both cases, I

submitted expert reports on: (1) differences between EndoWrist instruments and traditional laparoscopic instruments; (2) Intuitive's design control and risk management processes for EndoWrist instruments; (3) Intuitive's life testing of EndoWrist instruments; (4) the "EndoWrist Service Procedure" employed by Rebotix and Restore, respectively; (5) Rebotix's risk management activities; and (6) Rebotix's life testing. In *Restore Robotics*, my expert report also discussed Restore's "service" procedures for da Vinci surgical systems. I also provided a supplemental expert report in *Restore Robotics* discussing the FDA's recent clearance of Iconocare Health's 510(k) application, which permits Iconocare to market a remanufactured S/Si 8mm Monopolar Curved Scissor instrument reset one time with ten additional lives (for a total of up to 19).

5. In *Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc.*, I submitted an expert report on: (1) differences between EndoWrist instruments and traditional laparoscopic instruments; (2) the "EndoWrist Service Procedure" employed by Rebotix on behalf of SIS; (3) SIS's assumption that Rebotix's service procedure is safe and reliable; (4) SIS's reliance on Rebotix's risk management and life testing; and (5) Rebotix's risk management activities and life testing.

6. My education and experience in these fields are set forth in detail in my attached curriculum vitae, attached as Appendix A of this Report, which includes a list of publications authored in the previous 10 years and a list of all other cases in which I have testified or been deposed in the past four years.

II. Assignment

7. I have been retained by counsel from the law firm Skadden, Arps, Slate, Meagher & Flom LLP on behalf of its client, Intuitive Surgical, Inc. ("Intuitive"), concerning a dispute between Intuitive and Larkin Community Hospital ("Larkin"), Franciscan Alliance, Inc.

(“Franciscan”), and King County Public Hospital District No. 1, DBA Valley Medical Center (“Valley Medical”) (collectively, “Plaintiffs”). In particular, I have been asked to provide opinions on the safety and reliability of the services performed by third parties on EndoWrists and the Intuitive systems. This includes responding to certain opinions offered in the expert reports of Einer Elhauge, Eugene Rubach, and Kimberly Trautman, provided in support of Plaintiffs’ claims. My general understanding of the dispute as it relates to my Report and analysis is as follows.

8. Intuitive designs, manufactures, and markets the da Vinci robotic-assisted surgical system (“da Vinci”), along with its associated instruments, including EndoWrist instruments, for use in minimally invasive surgery. Certain da Vinci instruments, such as EndoWrist instruments, incorporate a usage limit on the number of procedures that can be performed, after which the instrument must be replaced. As Intuitive explains in its Answer, “it has conducted rigorous testing and identified a maximum use limit for EndoWrists,” and “the maximum use limit ensures that instruments perform safely and reliably.”¹

9. Plaintiffs are Larkin, a Miami-based hospital²; Franciscan, a 13-campus healthcare system in the Midwest³; and Valley Medical, a Seattle-area hospital.⁴ Each of the three Plaintiffs owns or leases one or more da Vinci surgical systems.⁵

10. Surgical Instrument Service Company, Inc. (“SIS”) is a third party that has offered certain services in connection with da Vinci robotic-assisted surgical systems, including

¹ Defendant Intuitive Surgical, Inc.’s Answer, ¶ 96 (filed Jan. 18, 2022).

² Consolidated Am. Class Action Compl. (“Hospital Compl.”) ¶ 10 (filed Sept. 10, 2021).

³ *Id.* ¶ 14.

⁴ *Id.* ¶ 18.

⁵ *Id.* ¶¶ 11, 15, 19.

for certain EndoWrist instruments that can be used with the S and Si da Vinci Surgical systems.⁶ SIS facilitated for its customers a “reset service” that bypasses the original usage limits of EndoWrist instruments to enable end-users to keep using the EndoWrist instruments beyond those built-in limits. SIS did not perform the reset process itself, but instead relied entirely on a third-party, Rebotix Repair LLC (“Rebotix”).⁷ SIS simply facilitated EndoWrist instrument resetting for its customers by Rebotix.⁸ Rebotix is able to bypass Intuitive’s usage counter by inserting a “Rebotix Interceptor” into EndoWrist instruments, which according to Rebotix, resets the usage counter.

11. Another third party, Restore Robotics LLC (collectively with its related entity Restore Robotics Repairs LLC, “Restore”) also offered certain services in connection with da Vinci robotic-assisted surgical systems, including for EndoWrist instruments that can be used with the S and Si da Vinci Surgical systems. Like SIS, Restore offered a “service” that bypassed the original usage limits of EndoWrist instruments, utilizing the Interceptor technology developed by Rebotix, so that end-users could continue using EndoWrist instruments beyond those built-in limits. In addition to bypassing the usage limits on EndoWrist instruments, Restore also offered to customers servicing of the da Vinci robotic surgical system.

⁶ EndoWrist Instruments that can be used with Intuitive’s S and Si da Vinci systems are often referred to as S and Si instruments. In addition, most of Intuitive’s internal engineering and technical documents refer to the S and Si systems as the IS2000 and IS3000 systems and refer to the EndoWrist instruments as IS2000 and IS3000 instruments, respectively.

⁷ Oct. 27, 2022 Keith Johnson 30(b)(6) Tr. at 33:22-34:2 (“[Q.] My question was: Did SIS ever actually perform the [EndoWrist repair] service in-house. A. No. Q. So for all of the EndoWrist repairs that SIS facilitated, those repairs were actually performed by Rebotix; correct? . . . A. Correct.”); *see also* Nov. 1, 2022 Greg Posdal 30(b)(6) Tr. at 22:10-12 (“Q. SIS does not itself perform the resetting process; correct? A. It -- that is correct.”).

⁸ Oct. 27, 2022 Keith Johnson 30(b)(6) Tr. at 33:25-34:4.

12. [REDACTED]

[REDACTED]

13. I was asked to review the record information in this matter regarding Intuitive's mechanical design of the EndoWrist instruments and the scientific testing performed to validate the EndoWrist usage limits. I was also asked to review the available information regarding the development of the Rebotix Interceptor, the installation of the Rebotix Interceptor, and any testing (or lack of testing) that Restore, Rebotix, or SIS performed to determine whether bypassing the EndoWrist's usage limits was mechanically viable or safe and reliable for patient use. I was also asked to review information regarding the Iconocare Process, and assess any differences between the Restore/Rebotix Process and the Iconocare Process, as well as the risk management and life data supporting each process. Finally, I was asked to review information regarding Intuitive's da Vinci system service, maintenance, and repair procedures compared to information relating to Restore's da Vinci System "service" offering.

14. What follows is a Report on my findings after a review of the relevant materials, which were identified through an examination of documents produced in the litigation, Plaintiffs' Amended Complaint (ECF No. 52) ("Hospital Complaint"), Defendant Intuitive Surgical, Inc.'s

9 [REDACTED]

Answer and Affirmative Defense (ECF No. 74), a review of testimony provided by witnesses at deposition, and a review of Plaintiffs' written discovery responses. A list of materials I considered in connection with this matter is attached as Appendix B of this Report.

15. I am being compensated for my work at the rate of \$600 per hour. My compensation is in no way dependent on the outcome of this matter. Additional time required for trial testimony or deposition will also be billed at the rate of \$600. I was supported in this matter by a postdoctoral research associate in the Harvard Paulson School of Engineering and Applied Sciences, Dr. Richard Nuckols, who was compensated for his work at the rate of \$125 per hour.

III. Summary of Opinions

16. It is my opinion that there are significant differences between EndoWrist instruments and traditional laparoscopic instruments, and that these differences contribute to EndoWrist instruments having a shorter useful life than traditional laparoscopic instruments. Unlike traditional laparoscopic instruments, EndoWrists have a set of mechanical joints (or "wrists") at their distal end¹⁰ which permit three degrees of freedom of movement (as compared to one or at most two degrees of freedom in typical traditional laparoscopic instruments). These additional degrees of movement in EndoWrists are made possible by the use of cables and pulleys within the instrument. While the cable and pulley mechanisms utilized by EndoWrist instruments permit additional degrees of movement and dexterity, they are less durable and more prone to mechanical failure over an extended period of use than the drive rods typically utilized in traditional laparoscopic instruments. There is thus a tradeoff whereby EndoWrist instruments

¹⁰ The distal end, as the term is used regarding EndoWrist instruments, is the portion of the instrument that interacts with the patient to perform a function during a surgical procedure. The other end, referred to as the proximal end, is the portion of the instrument that connects to the da Vinci surgical system.

permit increased dexterity and freedom of motion but fewer uses as compared to traditional laparoscopic instruments.

17. It is my opinion that Intuitive maintains rigorous design control and risk management processes which illuminate, and allow Intuitive to account for, the various risks or potential failure modes associated with the EndoWrist instruments. Intuitive's comprehensive design control processes allow Intuitive to design instruments so as to support reliable and consistent performance over a prescribed number of uses.

18. It is my opinion that Intuitive's rigorous testing of its EndoWrist instruments adequately reflects the stresses and forces that instruments are subjected to during clinical use and demonstrates that instruments can only be reliably used a limited number of times. Both Intuitive's life testing and actual, clinical results demonstrate that EndoWrist instruments experience significant wear and tear during their prescribed useful life.

19. It is my opinion that although Rebotix, Restore, and SIS refer to the "reset" services as a "repair,"¹¹ Rebotix simply devised a method that intercepts communication between the robot and the instrument in order to circumvent the usage limits implemented in each EndoWrist instrument, without adequately addressing the effects of wear and tear that accrue during instrument usage.

20. It is my opinion that there are numerous deficiencies in Rebotix's "EndoWrist Service Procedure" (the "Rebotix Process"),¹² which Restore also employed¹³. The steps performed during the Rebotix Process fail to adequately address many of the risks associated

¹¹ Def.'s Ex. 136, SIS095115-095139, at SIS095120.

¹² See REBOTIX162404 (described *infra* § VI).

¹³ See Restore-00001538

with extending the number of times an EndoWrist instrument may be used beyond the prescribed usage limit, such as the risks of mechanical failure by components within the instrument's proximal housing. This increased risk of failure would not necessarily be evident based on a visual inspection of the instrument by a surgeon or hospital staff. Moreover, there are numerous ways the Rebotix Process may introduce additional risks to instrument functionality and increase the likelihood of the failure modes identified by Intuitive during their own life testing.

21. It is my opinion that Rebotix's risk management activities with respect to extending the lives of EndoWrist instruments are inadequate. Rebotix's risk management activities with respect to extending the life of the EndoWrist instruments assume that the Rebotix servicing procedure is adequate to restore the instruments to equivalent specifications to new instruments, but do not consider the deleterious effects of previous surgical uses and sterilization procedures, which have been clearly shown to decrease reliability. In addition, they do not adequately address the risks of mechanical failure associated with using an EndoWrist instrument beyond the prescribed usage limit.

22. It is my opinion that Rebotix's life testing fails to adequately simulate the stresses and forces that instruments are subjected to during clinical use and therefore cannot reliably be said to validate the use of the EndoWrist instruments for uses beyond the prescribed usage limit.

23. It is my opinion that Restore and SIS relied entirely on Rebotix's risk management activities and life testing, and that the limited information available to them was not sufficient to determine whether the instrument was safe or reliable.

24. It is my opinion that Intuitive's position that it could potentially develop robust EndoWrist refurbishment procedures does not mean that Rebotix's resetting procedures were adequate.

25. It is my opinion that there are significant differences between the Rebotix Process for remanufacturing S/Si EndoWrist instruments and the Iconocare Process for remanufacturing the S/Si 8mm Monopolar Curved Scissor EndoWrist, and the Iconocare Process is likely to produce safer and more reliably-remanufactured instruments than the Rebotix Process.

26. It is my opinion that the risk management and life data submitted to the FDA for the Iconocare Process is significantly more robust than the risk management and life testing data Rebotix had access to in connection with the Rebotix Process.

27. It is my opinion that, while even a single EndoWrist reset introduces safety risks, there are significantly greater safety risks created by resetting an EndoWrist usage counter multiple times (as Restore and Rebotix claimed they could do with their processes) than by resetting the usage counter once (as called for by the Iconocare Process).

28. Finally, it is my opinion that the procedures performed by Restore to "service" da Vinci surgical systems contain significant deficiencies that do not allow proper maintenance or repair of da Vinci surgical robots, as evidenced in part by Restore's own admissions and significant shortcomings in the Restore "service" process.

29. Discovery is ongoing in this matter, and I reserve the right to amend or supplement my opinions and findings as additional material becomes available.

IV. The Intuitive EndoWrist Instrument and the Interceptor

A. Overview of Intuitive S/Si EndoWrist Instruments

30. EndoWrist instruments are designed for use in conjunction with the da Vinci surgical robot system. I first became aware of the EndoWrist instrument design through conversations with Dr. Ken Salisbury and Akhil Madhani, his doctoral student at MIT, soon after they invented these instruments in the mid-1990's. After their invention, I have had many EndoWrist instruments in my lab, which we analyzed as part of our research efforts on new surgical instrumentation. I have also had many opportunities to operate various models of the da Vinci robot, including an extended collaboration with surgeons at Boston Children's Hospital, where they had a robot dedicated to training and research that afforded me and my research group opportunities to perform experiments on sensing and control using the robot.

31. EndoWrist instruments are endoscopic instruments that access tissues within the patient's body through small incisions in order to minimize damage to healthy tissue. In contrast to conventional manually-driven endoscopic (laparoscopic) instruments, EndoWrist instruments have a set of mechanical joints located at the distal end. *See* Figure 1. This allows the surgeon to freely orient the end effector to perform dexterous maneuvers, which greatly enhances the ability to effectively and efficiently carry out minimally invasive surgical procedures.¹⁴

32. To provide the additional degrees of freedom at the surgical site compared to traditional laparoscopic instruments, EndoWrist instruments use a sophisticated cable drive mechanism. This innovative system was the subject of several issued US and international

¹⁴ *See* REBOTIX152284 at REBOTIX152297 (2014 Instrument and Accessories User Manual (S/Si instruments)). My descriptions of the features of EndoWrist instruments pertain to S and Si EndoWrist instruments, except for descriptions of the Xi instruments as specifically noted below.

patents.¹⁵ Four input pulleys on the proximal end of the instrument mate with motor drives in the surgical robot. These pulleys are connected to internal cables that control roll of the instrument shaft, yaw and pitch of the instrument wrist, and open/close of the end effector. These cables pass over idler pulleys, then through the elongated instrument shaft to the wrist, where they are routed over a series of pulleys to produce the intended motion. Inside the central length of the shaft, the cables are crimped onto rods to reduce the effects of cable stretch, but the cables wrap around pulleys in both the proximal and distal ends of the instrument. In addition to allowing the required degrees of freedom to fit within the constrained shaft diameter, the use of cables also enables a large range of motion in each degree of freedom.

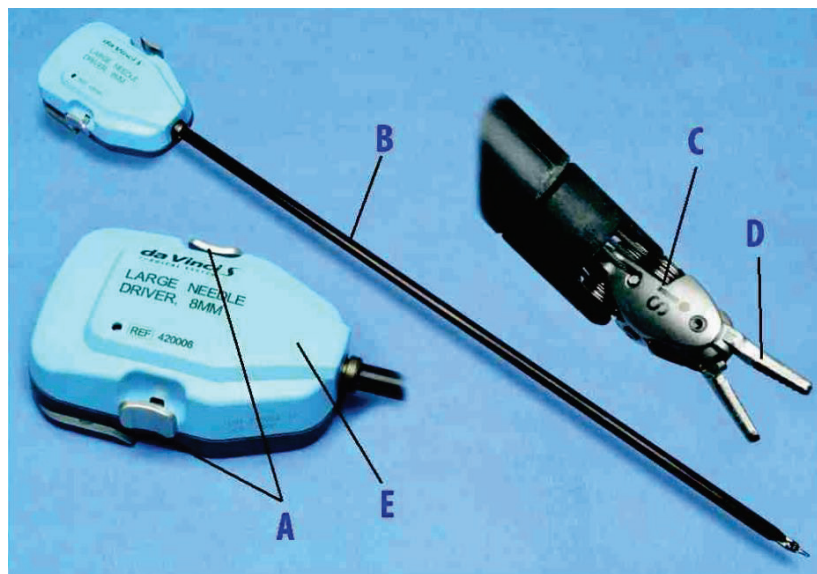


Figure 1.¹⁶

¹⁵ See, e.g., US Patent Nos. 5,797,900 (“Wrist Mechanism for Surgical Instrument for Performing Minimally Invasive Surgery with Enhance Dexterity and Sensitivity”) and 6,991,627 (“Articulated Surgical Instrument for Performing Minimally Invasive Surgery with Enhanced Dexterity and Sensitivity”).

¹⁶ REBOTIX152284 at REBOTIX152297 (Intuitive 2014 Instrument and Accessories User Manual (S/Si instruments)). The figure above demonstrates that EndoWrist Instruments consist of five main components: the Release Levers (A); the Instrument Shaft (B); the Wrist (C); the Tip or End Effector (D); and the Instrument Housing (E). REBOTIX152284 at REBOTIX152297.

33. An essential part of the specifications for the EndoWrist instruments is a limitation on the number of times each instrument can be used for surgical procedures.¹⁷ In S and Si instruments, the limitation is implemented through an integrated circuit that keeps track of the number of times the instrument is used in a surgical procedure by a da Vinci robot. This chip, a Maxim/Dallas Semiconductor DS2505 (sometimes referred to as the “Dallas chip”) resides on a small printed circuit board in the proximal housing of each instrument. It is an add-only memory that communicates with the robot over a one-wire bus, where additional data can be programmed into EPROM without disturbing existing data, and each memory page can be permanently write-protected to prevent tampering. In addition, each chip has a unique factory-set serial number.¹⁸ These features provide a secure means for keeping track of the number of uses. During manufacturing, the DS2505 chip is programmed with the total number of allowed uses; for most S and Si EndoWrist instruments, this usage limit is ten surgical procedures.¹⁹ When an instrument is connected to a da Vinci robot, the robot’s controllers communicate with the chip over the one-wire bus via a pogo pin connector in the proximal housing. The robot queries the chip for stored information, including the number of previous uses. If the uses have been decremented to zero, the robot will not activate the instrument. If the robot commences with use

¹⁷ As described further below, the specifications for EndoWrist instruments are detailed in a series of documents, which include Architectural Requirement Documents (“ARDs”) and Functional Requirements Documents (“FRDs”), among others. The ARD for the IS1200, IS2000 and IS3000 Instruments provide that the instruments “shall be programmed with the number of uses as specified in the individual Instrument Functional Requirements.” Intuitive-00538487 at Intuitive-00538496. The FRDs contain the specific requirements for individual instruments and set out the maximum number of times each type of instrument may be used. *See* Intuitive-00539807.

¹⁸ *See* DS2505 Dallas Semiconductor data sheet, available at: <https://datasheets.maximintegrated.com/en/ds/DS2505.pdf>; *see also* Intuitive-00538487 at Intuitive-00538496 (describing Dallas Chip Interface Requirements for EndoWrist instruments).

¹⁹ *See* Intuitive-00539807 (FRD) (setting out usage limits).

of the instrument for the surgical procedure, the number of uses stored in the chip is decremented by one.²⁰ In X/Xi instruments, the usage limitation is implemented through an RFID chip that communicates the use counter information and other data from the EndoWrist to the da Vinci system itself.²¹

B. Differences Between Intuitive EndoWrist Instruments and Traditional Laparoscopic Instruments

34. Plaintiffs allege that the “sole purpose” of use limitations on EndoWrists “is to artificially inflate the number of EndoWrists hospitals must purchase.”²² Plaintiffs’ experts assert that “[m]anual laparoscopic instruments have ‘very, very similar’ materials and components to EndoWrists.”²³ Plaintiffs’ experts also assert that the use limits on EndoWrists are “artificially low,” “artificially suppress[ed],” and “arbitrary.”²⁴ Contrary to Plaintiffs’ claims, there are a number of features that are unique to EndoWrist instruments as compared to those in traditional laparoscopic instruments, and these features necessitate limitations on the number of times each EndoWrist can be used safely and reliably.

35. Traditional endoscopic instruments differ in essential ways from EndoWrist instruments. I have observed the use of traditional endoscopic instruments in dozens of laparoscopic and thoracoscopic surgical procedures, and my lab has analyzed their design and function as part of our own efforts to develop minimally invasive surgical instrumentation. Both traditional endoscopic and EndoWrist instruments have an elongated shaft to enable surgeons to

²⁰ See, e.g., BB000011.

²¹ Nov. 8, 2022 Grant Duque 30(b)(6) Tr. at 22:5–23:17; Nov. 4, 2022 Sharathchandra Somayaji Tr. at 108:18–109:22.

²² Hospital Compl., ¶ 4.

²³ Expert Report of Einer Elhauge (Dec. 1, 2022) (“Elhauge Rep.”), ¶ 155.

²⁴ Elhauge Rep. ¶¶ 340, 348, 358–60, 363; Expert Report of Dr. Eugene Rubach (Dec. 1, 2022) (“Rubach Rep.”) ¶¶ 28–36.

work through a small incision. However, both the proximal and distal ends of EndoWrist instruments are significantly different than traditional endoscopic instruments, as is the mechanical connection between the ends. At the proximal end, traditional instruments have handles (typically a pair of levers or finger loops), which surgeons hold in their hands to apply forces and motions to the instrument and to open and close an end effector like scissor blades or forceps jaws (typical examples are shown in Figure 2). In contrast, EndoWrist instruments connect to a set of motor drives through four pulleys. *See* Figure 3.

36. The motor interface of an EndoWrist instrument introduces a number of constraints and potential failure modes to the instrument design that are not present in manual instruments. Examples of failures identified and considered by Intuitive engineers in designing the EndoWrist instruments include the possibility that the pins (or “dogs”) on the input pulleys would slip or shear off, potentially resulting in loss of control of the instrument.²⁵ Similarly, the bearings that enable low-friction motion of the input pulleys and shafts can fail, potentially resulting in loss of instrument functionality and/or having the bearings or their fragments fall into the patient.²⁶ There are no analogous parts to these two examples in conventional endoscopic surgical instruments. Additional examples of potential failures that pertain to the motor interface of EndoWrist instruments are detailed by Intuitive through their design control and risk assessment process.²⁷

²⁵ *See, e.g.*, Intuitive-00538994 at Tab 10, Rows 17-18.

²⁶ *See, e.g., id.* at Tab 11, Row 11.

²⁷ *See generally id.*



Figure 2.²⁸

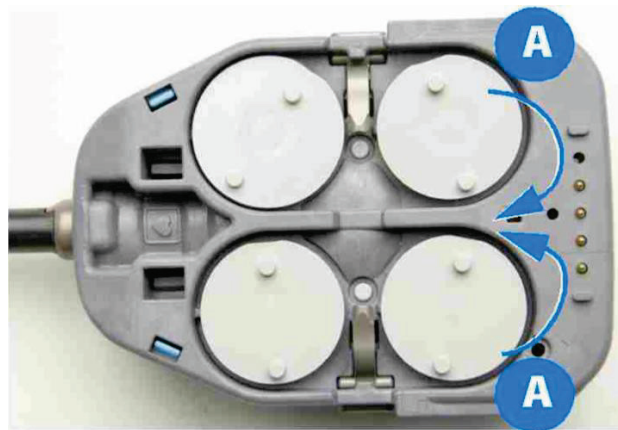


Figure 3.²⁹

37. EndoWrist instruments have unique capabilities that are not available with conventional endoscopic instruments. In particular, the wrist mechanism provides three degrees of freedom at the end of the instrument, often referred to as wrist yaw, wrist pitch, and grip. This contrasts with conventional endoscopic instruments that typically have one or at most two

²⁸ “Access and instruments product catalog” Medtronic, 2020, available at: <https://www.medtronic.com/content/dam/covidien/library/us/en/product/hand-instruments-and-ligation/access-instrumentation-products-catalog.pdf>.

²⁹ REBOTIX152284 at REBOTIX152360.

degrees of freedom. This provides the dexterity that allows surgeons using the da Vinci robot to perform some minimally invasive surgical procedures that are difficult or impossible to perform with conventional endoscopic instruments. While some manual instrument designs have attempted to provide additional degrees of freedom at the distal end, these have proved difficult to control in a dexterous manner; typically, an extra degree of freedom in tip orientation is manually set to a specific angle and left unchanged during subsequent maneuvers. The combination of the difficulty of control of additional degrees of freedom as well as their increased costs means that traditional endoscopic instruments do not provide the motion capabilities that EndoWrist instruments deliver. In contrast, the relative simplicity of conventional endoscopic instruments means that they can use much simpler, more robust, and less expensive drive mechanisms to fit in the constraints of shaft diameter. By far the most common design uses push-pull drive rods that pass through the instrument shaft to operate the distal degree(s) of freedom. These mechanisms are simple to design and are robust because they operate in simple loading conditions that are accurate to model during design and robust during operation, in contrast to the cable drives in EndoWrist instruments. As a result, traditional instruments are more resilient to fatigue, corrosion, and wear.³⁰

38. Because the EndoWrist instruments are driven by motors under computer control, they are also subject to high forces due to collisions that are not present for manual instruments. When a surgeon uses the control inputs to command an instrument to move along a path that intersects with another instrument, the ensuing collision can prevent the instrument from going to the commanded location. The instrument controllers can then generate high motor

³⁰ Richard G. Budynas and J. Keith Nisbett, *Shigley's Mechanical Engineering Design*, Ninth Edition, McGraw- Hill, New York, 2008, Chapters 3-5.

forces in an attempt to move the instrument as commanded, resulting in high forces applied to the instrument, particularly the wrist. This type of interaction is not present for manual laparoscopic instruments, where instrument motions are directly generated by the surgeon's hands and collisions result in far lower forces.

39. Unlike drive rods, cable drives (often alternatively referred to as “wire rope drives”) are more complex to design, particularly for high reliability across product life. Designers of wire cable or rope drives frequently focus on wear and fatigue issues. For example, a leading textbook on mechanical design elucidates these issues in the context of the interaction between the rope and the pulleys (or “sheaves”) over which it passes:

Once you have made a tentative selection of a rope based upon static strength, the next consideration is to ensure that the wear life of the rope and the sheave or sheaves meets certain requirements. When a loaded rope is bent over a sheave, the rope stretches like a spring, rubs against the sheave, and causes wear of both the rope and the sheave . . . The allowable pressures given in Table 17-26 are to be used only as a rough guide; they may not prevent a fatigue failure or severe wear. They are presented here because they represent past practice and furnish a starting point in design. . . . In view of the fact that the life of wire rope used over sheaves is only finite, it is extremely important that the designer specify and insist that periodic inspection, lubrication, and maintenance procedures be carried out during the life of the rope.³¹

40. The EndoWrist design is particularly challenging because of its small size and multiple degrees of freedom. *See* Figure 4.

³¹ Richard G. Budynas and J. Keith Nisbett, *Shigley's Mechanical Engineering Design*, Ninth Edition, McGraw- Hill, New York, 2008, Chapter 7, pp. 919-921.

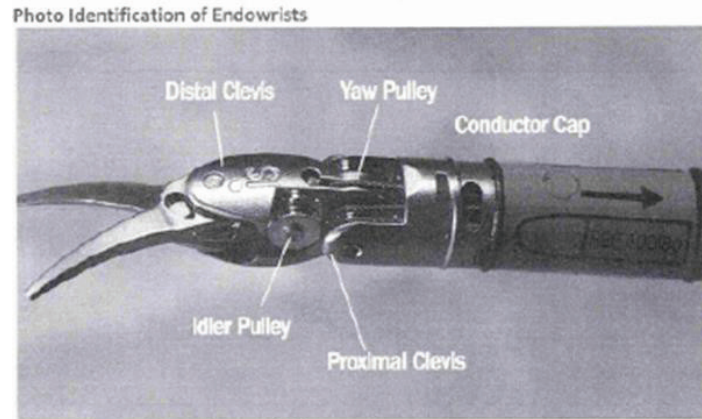


Figure 13 Monopolar Curved Scissors 420170

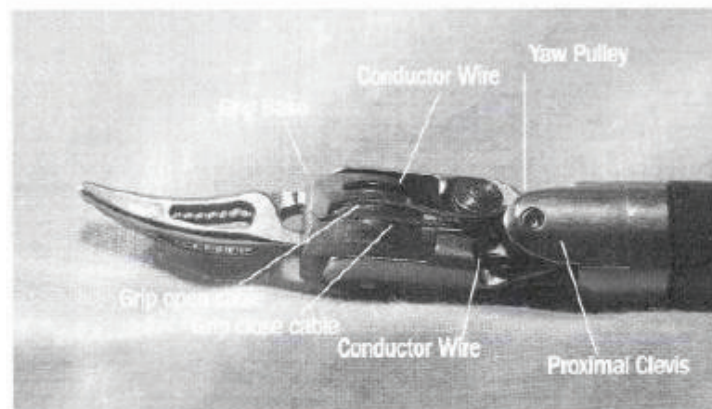


Figure 14 Maryland Bipolar Forceps 420172

Version vs Cause

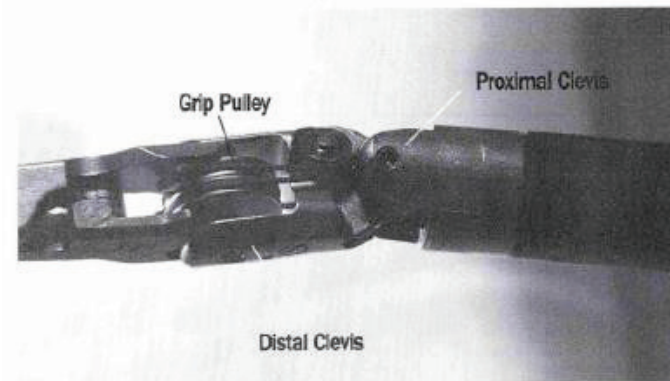


Figure 15 Prograsp Endowrist

Figure 4.³²

³² REBOTIX090153 at REBOTIX090226-227.

The result is that the cables pass over multiple pulleys in alternating directions. This is known to reduce the life of the cables:



Figure 4-8. Reverse Bend

To maximize the service life of a wire rope, it should be reeved (or threaded) through a block and tackle system with a minimum number of sheaves and the fewest possible reverse bends. Reverse bends, as shown in Figure 4-8, occur when the rope bends over a sheave in one direction, then under another in the opposite direction within a distance short enough so that a section of the rope traverses both sheaves. Bending fatigue due to this condition will reduce life to half of that experienced with only single-direction bends.³³

41. The cleaning and sterilization cycles to which EndoWrist instruments are repeatedly subjected are particularly detrimental to continuing reliable operation. Intuitive documents describe the impact on reliability of these reprocessing cycles. For example:

Ideally, the number of instrument uses is equal to its number of reprocessing cycles. However, depending on the practices of a hospital, instruments may undergo more reprocessing cycles than they do uses. Number of uses can be different from the number of reprocessing cycles when an instrument is brought into a sterile field, but is not put on the system and used by the surgeon. The instrument would still need to be reprocessed because it became contaminated by the surgical field, but, since the system-instrument interaction is what deducts the number of instrument lives, the number of uses remaining would remain unchanged. Current reliability testing accounts for these additional reprocessing cycles by testing to 5 additional reprocessing cycles to the

³³ U.S. Navy Wire-Rope Handbook, Vol. 1, p. 4-11.

Weibull analysis. When the number of reprocessing cycles far outnumber the number of uses, early failures can occur.³⁴

42. The corrosion that results from reprocessing is well-known to degrade wire rope drives:

Corrosion accelerates wire-rope deterioration. It reduces rope metallic area, limits flexibility, and leads to uneven wire surfaces that may cause damage to equipment and internal damage to the rope. Corrosion within a wire rope is almost impossible to detect visually, which makes it extremely difficult to determine the true condition of a corroded rope.³⁵

43. Plaintiffs' reliance on Intuitive's premarket 510(k) notifications to suggest equivalence between traditional endoscopic instruments and EndoWrist instruments³⁶ is misplaced. As explained in detail above, the internal drive mechanisms of EndoWrists and traditional instruments are very different. Thus, although they are in many external and functional ways similar to traditional instruments, the cable drive system is significantly different from traditional laparoscopic instruments and does not allow for unlimited, reliable surgical uses.

44. Intuitive designs take these principles into account. To account for potential fatigue and wear failure, the designs are life tested and are limited to a defined number of procedures that are consistent with the reliability demonstrated in these tests. The need for these precautions is clear from the observed life test failures and RMA returned instrument failures.³⁷

45. As additional support for the claim that Intuitive's use limits are arbitrary, Plaintiffs allege that the "surgical instruments used with Asensus' Senhance do not have use limits" and that "[t]raditional laparoscopic instruments do not have use limits."³⁸ This is not a

³⁴ Intuitive-00004692 at Intuitive-00004699-700.

³⁵ U.S. Navy Wire-Rope Handbook, Vol. 1, pp. 3-15–3-16.

³⁶ *See, e.g.*, Hospital Compl. ¶ 136.

³⁷ *See generally* Intuitive-00004692.

³⁸ Hospital Compl. ¶ 116; *see also* Elhauge Rep. ¶ 154.

meaningful comparison because the cited robotic instruments do not have the same functionality or capabilities as EndoWrist instruments. Almost all Asensus Senhance instruments do not have wrists;³⁹ this robot platform is designed to perform procedures that can be accomplished with conventional laparoscopic instruments, which, as explained above, have much lower dexterity than the da Vinci robot.⁴⁰ The three instruments with wrists listed in the Asensus Senhance catalog have only a single direction of articulation at the wrist (as opposed to the two directions on EndoWrists), and that wrist portion is a single-use disposable.⁴¹ Asensus does not offer a wristed instrument with unlimited uses.⁴²

46. Similarly, Medrobotics' Flex robot instruments do not have wrists.⁴³ The instruments are not powered, and all motions of the instrument tips are generated by motions of the surgeon's hands on the instrument control handles.⁴⁴ Because these instruments are constrained to fit through the working channel of a flexible endoscope robot, they do not have rigid shafts, and they have a greatly restricted range of motion compared to EndoWrist

³⁹ Senhance Surgical System EMEA Product Catalog, January 2020.

⁴⁰ See [Senhance.com/indications](https://www.senhance.com/indications) (explaining that "The Senhance® Surgical System is intended to assist in the accurate control of laparoscopic instruments . . . in general laparoscopic surgical procedures and laparoscopic gynecological surgery").

⁴¹ Senhance Surgical System EMEA Product Catalog, January 2020 at 7.

⁴² *Id.*

⁴³ See "Expanding the Reach of Surgery," Medrobotics "Flex" brochure, available at: <https://www.easmed.com/main/wp-content/uploads/BROCHURE-Medrobotics-Transanaleasmed.pdf>; see also "Flex Robotic System Technology: How it Works," available at: <https://web.archive.org/web/20200815134035/https://medrobotics.com/gateway/technology/>; "Flexible 'open architecture' instrumentation," available at: <https://web.archive.org/web/20200923215331/https://medrobotics.com/gateway/instruments/>.

⁴⁴ See "Flex Robotic System Technology: How it Works," available at: <https://web.archive.org/web/20200815134035/https://medrobotics.com/gateway/technology/>.

instruments.⁴⁵ Medrobotics does not offer powered or wristed instruments, or instruments with dexterity comparable to the EndoWrist instruments.⁴⁶

47. In addition to the differences between EndoWrist instruments and traditional laparoscopic instruments highlighted above, EndoWrist instruments require calibration to achieve specified performance. In particular, individual drive cable assemblies are pre-tensioned to specific values in a way that counteracts the anticipated cable-stretch over the life of the instrument.⁴⁷ Cable tensioning protocols require test fixtures, torque measurement instruments, and accurate execution of a multi-step protocol.⁴⁸ This complicated process is not used for traditional instruments that do not require similar calibration. In this way, I would not expect EndoWrist instruments and traditional instruments to have the same service life.

C. Overview of Interceptor Technology

48. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

⁴⁵ See “Expanding the Reach of Surgery,” Medrobotics brochure, available at: <https://www.easmed.com/main/wp-content/uploads/BROCHURE-Medrobotics-Transanaleasmed.pdf>.

⁴⁶ Furthermore, although Asensus’ and Medrobotics’ Flex robots may not specify a usage limit, their usage and durability in the field is not well understood as they have not yet been on the market nearly as long or as widely adopted as Intuitive’s EndoWrist instruments.

⁴⁷ See Intuitive-00537574 at Intuitive-00537575.

⁴⁸ See Intuitive-00705141 (Intuitive Manufacturing Process Instructions (MPI) Cable Tensioning, 838012).

⁴⁹ See *supra* ¶ 10; Nov. 1, 2022 Greg Posdal 30(b)(6) Tr. at 21:17-24.

50 [REDACTED]

[REDACTED]

49. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

50 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



*Figure 5.*⁵⁵

50. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

⁵⁵ REBOTIX100995 at REBOTIX101000.

[REDACTED]

51.

[REDACTED]

[REDACTED]

[REDACTED]

V. Intuitive's Design Control, Risk Management, and Testing Processes

A. Intuitive's Design Control and Risk Management Processes

52. Intuitive employs rigorous and in-depth design control and risk management processes. Without thorough design control and risk management, surgical robots could be hazardous to both patients and surgical staff. Potential risks for instruments for the da Vinci surgical robot system include: debris falling into the surgical field or patient, increased risk of electrical arcing/burning to patient tissue, unintuitive motion of the da Vinci surgical system,

⁵⁶ *Id.* at REBOTIX101001.

⁵⁷ *Id.* at REBOTIX101002-04.

inaccurate or sluggish motions of the EndoWrist instrument, inadequate or restricted ranges of motion, and the EndoWrist instrument failing to be recognized by the da Vinci surgical system.⁵⁸ Thus, measures to control risk are necessary throughout the product development and manufacturing process. Intuitive has an extensive system in place to evaluate and manage risk. This system is in accord with standard medical device industry practice.⁵⁹

1. Design Control

53. As described by the FDA, design controls “are an interrelated set of practices and procedures that are incorporated into the design and development process,” which result in earlier detection and correction of any “deficiencies in design input requirements, and discrepancies between the proposed designs and requirements.”⁶⁰

54. Intuitive describes its design control process as “[a] systematic framework used to demonstrate that the product works and that it meets the needs of the end-user (intended use) while maintaining safety and effectiveness.”⁶¹ Design control involves: (i) design verification, which considers and tests the engineering of a product, and (ii) design validation, which considers whether the product meets the needs of the end-user.⁶²

55. Within the design control framework, Intuitive’s development process involves detailing what a product must do through a Market Requirements Document (“MRD”) and

⁵⁸ See generally Intuitive-00538913, Intuitive-00538994.

⁵⁹ See generally Design Control Guidance for Medical Device Manufacturers, US Food and Drug Administration, available at: <https://www.fda.gov/media/116573/download>.

⁶⁰ *Id.* at 1 (“Design controls increase the likelihood that the design transferred to production will translate into a device that is appropriate for its intended use.”). This FDA guidance on design control for medical device manufacturers is applicable to new designs as well as modifications to existing device designs. *Id.* at 2.

⁶¹ Intuitive-00477325 at Intuitive-00477331.

⁶² Intuitive-00477217 at Intuitive-00477220; see also Intuitive-00477325 at Intuitive-00477331-32.

Product Requirements Documents (“PRD”).⁶³ These user and design needs are then implemented through Architectural Requirements Documents (“ARDs”), Functional Requirements Documents (“FRDs”), and lower level functional requirements and specifications.⁶⁴

2. Risk Management

56. Risk management is part of the design process and involves “the systematic application of management policies, procedures, and practices to the tasks of identifying, analyzing, controlling, and monitoring risk.”⁶⁵ As described more fully below and reflected in Figure 6, Intuitive’s risk management processes are integrated into the design control process and continue through the life of a product.⁶⁶

⁶³ Intuitive-00477217 at Intuitive-00477222; *see also* Intuitive-00477325 at Intuitive-00477358.

⁶⁴ Intuitive-00477217 at Intuitive-00477222; *see also* Intuitive-00477325 at Intuitive-00477364.

⁶⁵ Design Control Guidance for Medical Device Manufacturers, US Food and Drug Administration, at 5, available at: <https://www.fda.gov/media/116573/download>.

⁶⁶ Intuitive-00477422 at Intuitive-00477424.



*Figure 6.*⁶⁷

57. The Intuitive risk management process analyzes “risks in design and process, defines requirements to mitigate them, uses design control to trace them to tests, and analyses *[sic]* residual risk.” The risk analysis incorporates both a top-down and bottom-up approach.⁶⁸

58. From a top-down perspective, major risk management procedures and the associated documentation include a clinical risk analysis (“CRA”) that is formulated early in the product development process. This procedure aims to define potential problems and mitigations

⁶⁷ Intuitive-00477422 at Intuitive-00477424.

⁶⁸ Intuitive-00477422 at Intuitive-00477424-25.

to guide product definition. The usability risk analysis (“URA”) is formulated after the product is defined and considers how it might be used and misused.⁶⁹

59. From a bottom-up perspective, Intuitive’s risk management procedures include several failure mode and effects analyses (“FMEA”), including Design FMEA, (“dFMEA”), Process FMEA (“pFMEA”), and Supplier Process FMEA (“spFMEA”). FMEA analysis is performed after the product or its manufacturing process have been designed, and looks at potential failures of components and the overall system.⁷⁰ These procedures—and additional risk management documents—are coordinated with the product design process and design control documents, including definition of user needs, design inputs and outputs, and formal design reviews.⁷¹ This process manages overall risk in the marketed products.

60. A dFMEA is the key method for defining specific risks in a medical device design. In Intuitive’s dFMEA process, the device is systematically reviewed to determine the ways it could fail and the effects of a failure.⁷² Each significant failure mode is assigned scores for the likelihood of occurrence, the severity of the consequences of failure, and the ability to detect the failure.⁷³ These scores can be combined to provide a measure of the risk priority. Important risks are then mitigated, i.e., changes to the design or the product use are implemented to reduce the risk.⁷⁴

⁶⁹ Intuitive-00477422 at Intuitive-00477425-26.

⁷⁰ Intuitive-00477422 at Intuitive-00477424-27.

⁷¹ Intuitive-00477217 at Intuitive-00477220-24; *see also generally* Intuitive-00477325.

⁷² *See generally* Intuitive-00477829.

⁷³ Intuitive-00477422 at Intuitive-00477457. *See generally* Intuitive-00477829.

⁷⁴ *See* Intuitive-00477422 at Intuitive-00477454-457; Intuitive-00477829 at Intuitive-00477844-45.

3. Design Verification and Validation

61. As previewed above, a key aspect of the design control and risk management process is design verification. FDA regulations require that medical device manufacturers perform design verification to “confirm that the design output meets the design input requirements.”⁷⁵ In other words, the design verification process aims to determine whether the performance specifications (design inputs) are met by the new device (design outputs).⁷⁶ The Intuitive design verification process is designed in accordance with these protocols. The goal of design verification is to objectively show that the device is built correctly from an engineering standpoint.⁷⁷

62. Design control and risk management also involve design validation. FDA regulations also require that medical device manufacturers “establish and maintain procedures for validating . . . device design,” which “ensure[s] that devices conform to defined user needs and intended uses, and . . . include[s] testing of production units under actual or simulated use conditions.”⁷⁸ The Intuitive design validation process is designed in accordance with these protocols. The goal of design validation is to objectively show that the device meets user needs.⁷⁹

⁷⁵ Design Control Guidance for Medical Device Manufacturers, US Food and Drug Administration, at 29, available at: <https://www.fda.gov/media/116573/download>.

⁷⁶ *Id.* at 29-30.

⁷⁷ See Intuitive-00477325 at Intuitive-00477381.

⁷⁸ Design Control Guidance for Medical Device Manufacturers, US Food and Drug Administration, at 33, available at: <https://www.fda.gov/media/116573/download>.

⁷⁹ See Intuitive-00477325 at Intuitive-00477381-82.

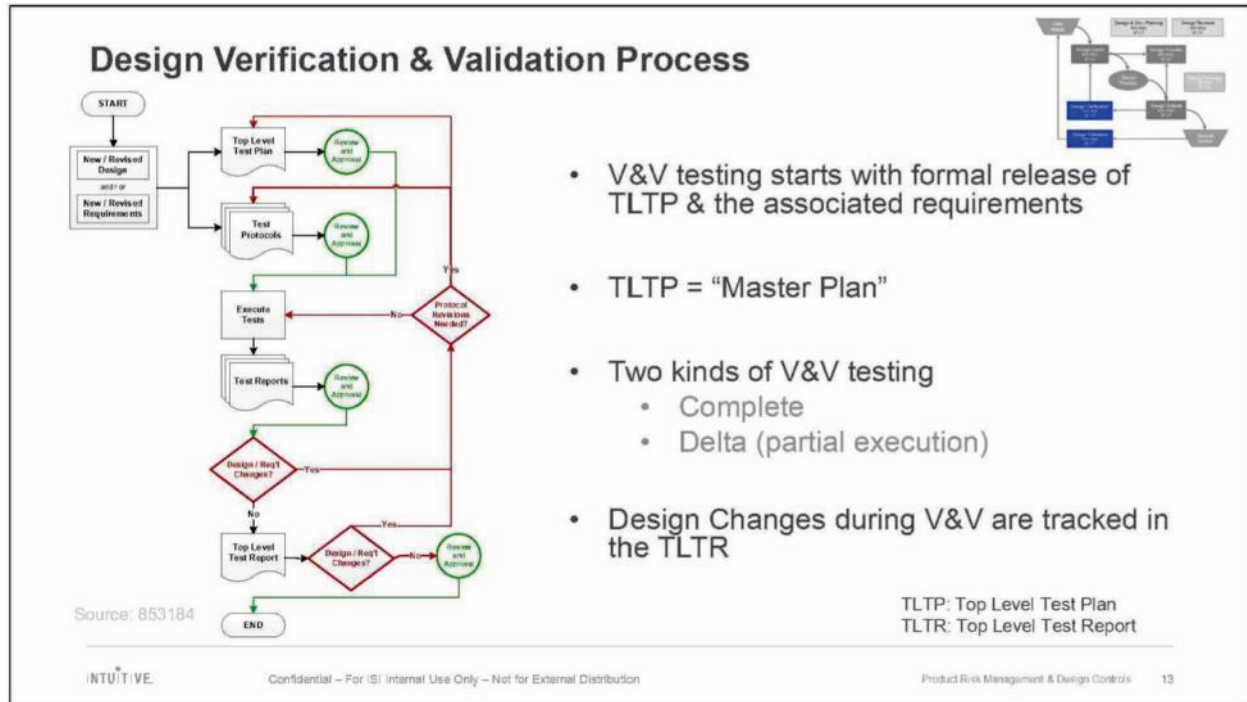


Figure 7.⁸⁰

63. Intuitive has a formal design verification and validation process. *See* Figure 7. Verification and validation testing of a new design or a design change begins with a Top Level Test Plan (“TLTP”) that describes the kinds of tests that are to be conducted and the analyses to be performed on the test data, as well as the justification for these tests that relates the specifications to the testing regimen.⁸¹ Test protocols detail the specific steps of each test and the procedure for documenting the testing process and the results. A Top Level Test Report (“TLTR”) summarizes the overall verification and validation results.⁸² Test reports present the results of the testing as well as analyses and conclusions. Additional documents that specify frequently-conducted test and analysis routines such as standard operating procedures (SOPs)

⁸⁰ Intuitive-00477217 at Intuitive-00477229.

⁸¹ Intuitive-00477217 at Intuitive-00477229.

⁸² *Id.*

and department operating procedures (DOPs) are used in formulating the test documents, which may be updated as appropriate throughout the verification process.⁸³ Testing may range from complete tests against specifications for new device designs to more limited “delta” tests for changes to existing designs.⁸⁴

B. Intuitive Designs and Tests Its EndoWrist Instruments to Reliably and Safely Perform Over a Set Number of “Lives”

64. Intuitive’s EndoWrist instruments are designed and tested to demonstrate the instruments are safe and effective and meet all of their specified requirements and specifications, including their programmed number of instrument uses, otherwise referred to as instrument “lives.”⁸⁵

65. To verify that the design of EndoWrist instruments meets the proposed number of surgical uses, Intuitive conducts life tests.⁸⁶ This process is typically documented by a “Protocol for Reliability/Life Testing” and a “Report for Reliability/Life Testing” or similar documents.⁸⁷ These test procedures typically include initial cleaning and sterilization cycles then alternating simulated surgical procedures, sometimes also referred to as a simulated surgical use (“SSU”), and cleaning and sterilization cycles, which in combination are referred to as Surgical Use Cases (“SUCs”) or life cycles. Attachments to these documents usually include sheets for recording the specific instruments undergoing testing, the equipment used, the observed

⁸³ See, e.g., Intuitive-00544199 (referencing, among other documents, Intuitive’s DOP, Product Verification and Validation (Intuitive-00477154); SOP, Statistical Techniques (Intuitive-00477757); and SOP, Risk Management (Intuitive-00477958)).

⁸⁴ Intuitive-00477217 at Intuitive-00477229.

⁸⁵ See generally Intuitive-00477154.

⁸⁶ See, e.g., Intuitive-00544199; Intuitive-00546380; Intuitive-00547846.

⁸⁷ See, e.g., Intuitive-00544199; Intuitive-00544494; Intuitive-00546380; Intuitive-00546343; Intuitive-00547846; Intuitive-00546920.

conditions during tests (e.g., sterilization temperatures), checklists for recording each step and the data that results from the tests.⁸⁸

66. A representative example of the Intuitive life testing process is captured in the set of documents describing the life test verification of the IS1200 and IS2000/IS3000 Mega SutureCut needle driver (MSCND) and Large SutureCut needle driver (LSCND).⁸⁹ The “Protocol for Reliability/Life Test of MSCND and LSCND Improvements for Grip Cable Life” details the testing process and its justification, as well as the steps required to document the test execution and the results.⁹⁰ This protocol describes the goal of the tests in terms of functional requirements (e.g., reliable operation for ten human uses) and the instrument models to which it applies, and uses a worst-case analysis to determine which specific instrument types are most likely to experience failure and thus should be tested.⁹¹

67. This protocol also uses a statistical Weibull Design of Reliability analysis to determine the number of instrument samples and use cycles that are required to statistically “prove” a number of instrument lives.⁹² The analysis applied in connection with the Protocol for Reliability/Life Test of MSCND and LSCND Improvements for Grip Cable Life uses a goal of 90% reliability and 90% confidence (“90/90”) for ten human uses.

68. This Protocol for Reliability/Life Test of MSCND and LSCND Improvements for Grip Cable Life is a test following a design change for “updating the proximal clevis pin”

⁸⁸ See, e.g., Intuitive-00544199 (describing attachments and checklists).

⁸⁹ See generally Intuitive-00544186; Intuitive-00544195; Intuitive-00544197; Intuitive-00544198; Intuitive-00544199; Intuitive-00544388.

⁹⁰ See generally Intuitive-00544199.

⁹¹ *Id.* at Intuitive-00544200.

⁹² *Id.* Weibull Design of Reliability analysis is further detailed in the Intuitive’s “Statistical Techniques – Department Operating Procedure,” Intuitive-00477757.

that was instituted to “reduce the occurrence of grip cable failures.”⁹³ The tests are designed to confirm that this change to the design maintains the specified level of reliability and confidence, so a relatively small sample size of eight units was tested due to the presence of a similar predicate device.⁹⁴ Each of these units is put through a total of 15 “life cycles,” which comprise an initial six cleaning and sterilization cycles, followed by fifteen simulated surgical uses and cleaning and sterilization cycles to validate 10 human surgical uses.⁹⁵

69. Simulated surgical procedures for life tests are described in the test report as “developed by the Clinical Development Engineering team.” *See* Figure 8. The simulated surgical procedure requires a series of maneuvers of the instrument that replicate how the instrument is used in an applicable laparoscopic surgical operation. *See* Figures 8, 9, 10. In the example of the life testing of the MSCND and LSCND instruments, these steps include wrist circles (moving the instrument tip in a circular pattern), needle throws (driving the needle through a single stitch), suture pulls, tissue lifts, and tissue pushes. *See* Figure 9. Animal tissue models (in this case a beef rib roast) or synthetic models are used to provide reaction forces that emulate the forces produced in surgical procedures. *See* Figure 11. For example, the tissue push maneuver is described as “[p]ush with a force of approximately 2 lbs”⁹⁶ Maneuvers are done in an order that replicates typical surgical usage and repeated a specific number of times that conservatively approximates repetitions in surgery.⁹⁷

⁹³ Intuitive-00544199 at Intuitive-00544201.

⁹⁴ Intuitive-00544494 at Intuitive-00544494.

⁹⁵ Intuitive-00544199 at Intuitive-00544200, Intuitive-00544209.

⁹⁶ *Id.* at Intuitive-00544201.

⁹⁷ *See* Intuitive-00544494 at Intuitive-00544496.

70. By defining a simulated surgical procedure based on observed maneuvers used in applicable laparoscopic surgeries, using animal tissue or synthetic models to emulate forces used in surgical procedures, performing maneuvers in an order replicating typical surgical usage and employing a conservative approximation of the number of maneuvers to be performed during an applicable laparoscopic surgical operation, Intuitive tests instruments in a way that helps ensure the instruments operate reliably and safely over their programmed number of instrument uses.

8. Definitions

- A) **Simulated Surgical Procedure** – A “Simulated Surgical Procedure” for the instrument was developed by the Clinical Development Engineering team. It is comprised of surgical tasks that are defined to represent actual maneuvers performed during minimally invasive surgical operations. The number of repetitions to be completed was determined by conservatively estimated the number of such maneuvers performed during an applicable laparoscopic surgical operation. Attachment 5 (Protocol 862287-01P) provides further details.

*Figure 8.*⁹⁸

⁹⁸ Intuitive-00544494 at Intuitive-00544496.



*Figure 9.*⁹⁹

⁹⁹ Intuitive-00544199 at Intuitive-00544201.

12 Simulated Surgical Procedure (SSP)

The following table defines a clinical life simulation cycle for the MSCND instrument. This cycle utilizes the motions defined above (see section 7) and arranges/distributes them in a way that more closely approximates the expected usage patterns.

MSCND, One (1) Simulated Life Use

# of executions	Task
1	Dip
10	Needle Throws, Forehand (using Beef Roast)
10	Needle Throws, Backhand (using Beef Roast)
1	Instrument Change
Repeat Above Two Times	
1	Dip
20	Wrist Circle, Grips Closed (but not squeezed)
30	Suture Pulls
1	Instrument Change
Repeat Above Six Times	
1	Dip
10	Tissue Lift, Release
10	Tissue Push, Release.
1	Instrument Change
Repeat Above Three Times	
1	Dip
10	Needle Throws, Forehand (using Beef Roast)
10	Needle Throws, Backhand (using Beef Roast)
1	Instrument Change
Perform Above a Single Time	
30	Suture cuts
Perform Above a Single Time	

Figure 10.¹⁰⁰

¹⁰⁰ Intuitive-00544199 at Intuitive-00544206.



Figure 11.¹⁰¹

71. As expected with a rigorous life testing process, failures are observed during life testing of Intuitive EndoWrist instruments. In the MSCND and LSCND example, one of the eight instruments under test suffered a failure on the fourth test cycle, when “the grip close cable derailed from the distal idler pulley during testing.”¹⁰² Other examples of life testing that resulted in failures includes:

- Life testing of the 8mm permanent cautery hook, where failures were observed in three of the twelve test instruments during SUC trials 12, 17 and 21.¹⁰³
- Life testing of 8mm monopolar curved scissors, where a derailment failure occurred in SUC trial 6.¹⁰⁴

¹⁰¹ Intuitive-00544456 at Intuitive-00544464.

¹⁰² Intuitive-00544494 at Intuitive-00544500; *see also id.* at Intuitive-00544497.

¹⁰³ Intuitive-00589150 at Intuitive-00589153.

¹⁰⁴ Intuitive-00546920 at Intuitive-00546920. Instrument intuitive motion also failed for a different instrument in SUC trial 11 and for two additional instruments in SUC trial 12. *See id.*

- Life testing of 8mm monopolar curved scissors where a cable break was observed during SUC trial 7.¹⁰⁵ (Note that Intuitive considers the IS2000/3000 and IS4000 Monopolar Curved Scissors to be equivalent in terms of their distal portions.)¹⁰⁶

72. As mentioned above, Intuitive has standard procedures for modeling the reliability of the instrument by fitting the life test data to a Weibull reliability model.¹⁰⁷ The Weibull Distribution is “a parameterized continuous probability distribution that is commonly used in failure analysis.”¹⁰⁸ Use of the Weibull model provides the ability to predict the reliability of the instrument as a function of number of uses, as well as uncertainty estimates (confidence intervals) for these estimates.¹⁰⁹ This model is also used to establish testing parameters such as sample size.¹¹⁰ The use of these procedures is important because it accounts for the potential for failures throughout a product’s useful life and ensures instruments meet minimum reliability requirements throughout that useful life.¹¹¹ The Weibull model is a well-recognized and appropriate method for modeling the reliability of instruments.

C. As EndoWrist Instruments Are Used in a Hospital Setting to Perform Surgical Procedures, They Experience Wear and Tear that Ultimately Leads to Instrument Failure.

73. Gradual degradation of an instrument over time is expected given the design of EndoWrist instruments and it is one of the risks that is identified through Intuitive’s risk analyses

¹⁰⁵ Intuitive-00546343 at Intuitive-00546360.

¹⁰⁶ See e.g., Intuitive-00546343. The IS4000 system is commercially known as the da Vinci Xi surgical system.

¹⁰⁷ See Intuitive-00477597.

¹⁰⁸ *Id.*

¹⁰⁹ See Intuitive-00477597; Intuitive-00477620.

¹¹⁰ See Intuitive-00477620.

¹¹¹ Intuitive-00477597 at Intuitive-00477597-98.

and life testing and is factored into EndoWrist usage limits. In addition to identified failure modes/gradual degradation inherent in normal usage, instruments are exposed to stresses by surgeons and hospital staff in the ordinary course of their use. Intuitive observes and tracks these failures in instruments that have been sold to customers and used on patients through its return material authorization (RMA) process. The RMA process allows for customers to return EndoWrist instruments that experience failure during their intended lives for a prorated discount.

74. As Intuitive notes, “RMA data is an indicator of instrument reliability because it is correlated to the number of reported instruments that do not meet performance requirements throughout their intended life. Although Intuitive performs life testing to quantify how many lives an instrument can be qualified for, there is some possibility that the assumptions made in the life testing methodology is not representative of real-world use. Although life testing is a validated process for qualifying instrument lives, Intuitive also confirms life testing data with RMA data trends, which originate from real-world use, rather than simulated surgical use, which follows methods generated within Intuitive. If RMA rates were to be misaligned with expected reliability predicted from life testing, then life testing would need to be modified to align with the reality observed through RMA rates. Neither RMA rates nor life testing is solely responsible for validating the safety of the extension of lives.”¹¹²

75. Instruments are returned to Intuitive through the RMA process due to observed or alleged problems or failure during warranty. Intuitive has identified a variety of instrument failures—within their established usage limits—through the RMA process, including:

- Cable breakages¹¹³;

¹¹² Intuitive-00004692 at Intuitive-0000470-01.

¹¹³ See e.g., Intuitive-00695006 (RMA data) at Tab 1 Row 37.

- Cable fraying¹¹⁴;
- Cable derailment¹¹⁵;
- Cable slack¹¹⁶;
- Abuse in cleaning¹¹⁷;
- Decreased electrical insulation in both cautery and non-cautery EndoWrist instruments¹¹⁸; and
- Electrode tips becoming pitted and discolored,¹¹⁹ among others.

76. These failures have been observed during the warranty period, which covers only the number of lives validated by Intuitive. This RMA data provides further evidence that EndoWrist instruments can—and do—fail at times, even within the number of lives set for their use. Further, because Intuitive observes through its RMA process many instrument failures that occur as a result of wear and tear, I would expect Restore’s and Rebotix’s attempts to increase instrument usage limits above the limits prescribed by Intuitive will only increase failure rates. Intuitive’s EndoWrist instruments have been used in millions of procedures, and Intuitive thus has a large amount of data from real-world use.¹²⁰ By contrast, there is minimal real-world use data from remanufactured instruments.

¹¹⁴ See e.g., *id.* at Tab 1 Row 54.

¹¹⁵ See e.g., *id.* at Tab 1 Row 697.

¹¹⁶ See e.g., *id.* at Tab 1 Row 5284.

¹¹⁷ See e.g., *id.* at Tab 1 Row 121.

¹¹⁸ See e.g., *id.* at Tab 1 Row 856, Row 3365.

¹¹⁹ See e.g., *id.* at Tab 1 Row 91783.

¹²⁰ For example, Intuitive’s systems were used for over 1.5 million procedures in 2021 alone. Intuitive Surgical, Inc., Annual Report 2021, <https://isrg.intuitive.com/static-files/704322bf-cb0d-4ed1-954c-8eb46a070f70>.

77. Via the RMA process, Intuitive also observes failures in instruments that have had their useful lives extended by third parties such as Restore and Rebotix, which were returned to Intuitive. Such failures include:

- Failure of instrument to be recognized by da Vinci surgical robot¹²¹;
- Abuse in cleaning¹²²;
- Broken or dislodged wires¹²³; and
- Damaged instrument components¹²⁴.

78. In addition, I have reviewed evidence produced by Restore of complaints it received from customers relating to failure of instruments which had usage limits extended, including:

- [REDACTED]
- [REDACTED]
- [REDACTED].

79. Based on the evidence I have observed and described above, [REDACTED]

[REDACTED]

[REDACTED]¹²⁸ [REDACTED]

¹²¹ See *id.* at Tab 2 Rows 15, 17, 44 and 47.

¹²² See *id.* at Tab 2 Row 24.

¹²³ See *id.* at Tab 2 Row 28-31.

¹²⁴ See *id.* at Tab 2 Rows 18, 28-31.

¹²⁵ Restore-00030379 at Restore-00030379.

¹²⁶ Restore-00001424 at Restore-00001424-31, 33-38.

¹²⁷ Restore-0001424 at Restore-00001424-31, 39.

¹²⁸ [REDACTED]

VI. Limitations and Risks of the Interceptor and “EndoWrist Service Procedure”

80. The Rebotix Interceptor and the “Endo Wrist Service Procedure” developed by Rebotix are purported to extend the reliable life of certain EndoWrist instruments to at least nine surgical uses beyond their usage limit.¹³⁰ However, significant problems exist with Rebotix’s approach such that in my opinion, Rebotix cannot *reliably or safely* extend the lives of EndoWrist instruments to an additional nine lives beyond their initial usage limit. In my opinion, Rebotix’s service procedure and its risk management and life testing methods are flawed, making Rebotix’s claim that it can reliably extend the lives of EndoWrist instruments unreliable and unsupportable.

81. Further, both Restore and SIS entirely relied on Rebotix’s risk management and life testing methods, rather than performing their own assessments of the reliability of extending the useful lives of EndoWrist instruments.¹³¹ Since Rebotix’s safety and reliability claims were

¹²⁹ See e.g., REBOTIX045741 at REBOTIX045741; REBOTIX000874 at REBOTIX000875; REBOTIX088383 at REBOTIX088386 (3 instruments); REBOTIX060630 at REBOTIX060630-31; REBOTIX082118 at REBOTIX082118-9 (2 instruments); REBOTIX084983 at REBOTIX084983-84; REBOTIX000664 at REBOTIX000664; Intuitive-00695006 at Tab 2 Rows 15, 17, 20, 24, 44, 47 (6 instruments); CRMC 295 at CRMC 306 (3 instruments).

¹³⁰ REBOTIX162404 at REBOTIX162404.

¹³¹ May 6, 2021 Kevin May Tr. at 54:17–55:8, 129:3–130:21, 164:15–165:20; June 8, 2021 Kevin May Tr. at 245:13–16; Nov. 1, 2022 Greg Posdal 30(b)(6) Tr. at 22:24–23:2, 23:23–24:1, 25:1–6, 29:6–11, 30:8–13, 32:4–6, 49:23–50:3.

unreliable and unsupportable, both Restore’s and SIS’s safety and reliability claims are therefore similarly unreliable and unsupportable.

A. Risks Associated with the Rebotix “EndoWrist Service Procedure”

82. Rebotix describes the installation of the Rebotix Interceptor in a document titled the “Endo Wrist Service Procedure.”¹³² In addition, I understand that Rebotix created a video for the purpose of demonstrating the Rebotix service procedure to customers, which I reviewed in connection with the “EndoWrist Service Procedure”.¹³³ Both the service procedure documentation and video demonstrate a number of deficiencies in the Rebotix Interceptor installation process that pose risks to both instrument functionality as well as patient safety.

83. The “EndoWrist Service Procedure” begins with a recitation of precautions, warnings, and safety information, and a list of required equipment, parts and supplies.¹³⁴ The initial steps of the “EndoWrist Service Procedure” include connecting the instrument to an electronic test fixture to access information about the instrument¹³⁵ and visual inspection of the instrument,¹³⁶ followed by dielectric and electrical resistance testing of cautery instruments.¹³⁷

¹³² See REBOTIX162404.

¹³³ Deposition testimony indicates that Rebotix’s EndoWrist “repair” processes was captured in REBOTIX175327, which was then shown to customers and potential customers, in order to demonstrate Rebotix’s services. June 22, 2021 Gibson Dep Tr. at 136:1-137:5, 171:20-172:12, 186:4-10.

¹³⁴ REBOTIX162404 at REBOTIX162405-08.

¹³⁵ The information accessed is: (1) the number of current available uses; (2) the EndoWrist’s Serial Number; (3) the EndoWrist Device Type; and (4) the DS2505 Serial Number. REBOTIX162404 at REBOTIX162411-13.

¹³⁶ REBOTIX162404 at REBOTIX162404-13.

¹³⁷ REBOTIX162404 at REBOTIX162413-17.

The proximal housing is then opened and visually inspected, and the injection port and tube are removed.¹³⁸

84. Next, in cases where the instrument has not previously had the Rebotix Interceptor installed, the original circuit board is removed. Removal of the original printed circuit board (the “PCB”) requires milling away an unspecified amount of material from the existing printed circuit board mounting and prying it from its mounting pins. The DS2505 chip that contains instrument usage data is desoldered from the original PCB and then resoldered on a new Interceptor PCB. A conformal coating is then manually applied to the new PCB and cured.¹³⁹

85. Next, Rebotix performs tool “repairs.” The instrument’s cables are manually tensioned and the jaws are aligned and sharpened using pliers and files, as relevant for the instrument type. Metal surfaces are then polished and the instrument is cleaned. Next, the Interceptor PCB is mounted in the instrument.¹⁴⁰ The original mounting clips are hammered flat and then replaced on the mounting pins. The injection port and tube are reinstalled, and the housing cover is replaced.¹⁴¹

86. The same tests that were run at the beginning of the service procedure are then repeated: Rebotix’s electronic test fixture is used to confirm that the number of available uses value is now “10” (and that all of the other information (e.g., EndoWrist serial number) remains unchanged), the same visual inspection that was performed pre-servicing is repeated, and the

¹³⁸ REBOTIX162404 at REBOTIX162418.

¹³⁹ REBOTIX162404 at REBOTIX162418-21.

¹⁴⁰ REBOTIX162404 at REBOTIX162422.

¹⁴¹ REBOTIX162404 at REBOTIX162422-23.

dielectric and electrical resistance testing of cautery instruments that were performed initially (pre-“repair”) are repeated as well.¹⁴²

87. There are a number of potential risks associated with Rebotix’s servicing of EndoWrist instruments as described in the “EndoWrist Service Procedure,” demonstrated in the video, and summarized above.

88. First, multiple steps in the procedure generate particulate debris, including:

- (1) “6.1.7 Use a Dremel with a small etching bit to remove a small amount of material from the PCB alignment pins”¹⁴³;
- (2) “6.1.11 Using the Dremel, drill bit, and drill stop (set to approx. 23mm) to drill the pilot hole for the Screw to be added later”¹⁴⁴;
- (3) “6.4.2.2. Files can be used to correct any misaligned or damaged grasper teeth”¹⁴⁵;
- (4) “6.4.2.3. For scissors . . . [i]f sharpening is needed, use the #6 and # 10 cut files to hone the cutting edges as needed”¹⁴⁶; and
- (5) “6.4.3.2. Under magnification, use the Dremel and the abrasive buff to lightly polish all metal surfaces to achieve a uniform satin finish.”¹⁴⁷

89. Notably, while each of these steps within Rebotix’s process generates particulate debris, methods for thoroughly removing this debris are not provided in the “EndoWrist Service Procedure,” and inadequate methods are prescribed. For example, after the drilling of a hole in

¹⁴² REBOTIX162404 at REBOTIX162424.

¹⁴³ REBOTIX162404 at REBOTIX162418.

¹⁴⁴ REBOTIX162404 at REBOTIX162419.

¹⁴⁵ REBOTIX162404 at REBOTIX162422.

¹⁴⁶ REBOTIX162404 at REBOTIX162422.

¹⁴⁷ REBOTIX162404 at REBOTIX162422.

the instrument, Rebotix recommends that the technician “brush off any debris created from the drilling process.”¹⁴⁸ Based on my experience, brushing is not effective for removal of debris from the complex internal geometry of the exposed instrument mechanism (including recesses and cavities) after the cover has been removed. In the service procedure video, Rebotix’s technician attempts to remove debris by blowing on the instrument with his mouth and brushing the instrument with his fingers, neither of which is an adequate means to effectively remove debris.¹⁴⁹ While earlier Rebotix documents refer to ultrasonic cleaning procedures for removing debris,¹⁵⁰ those procedures are not referenced or incorporated into Rebotix’s 2019 EndoWrist Service Procedure documentation.¹⁵¹ Additionally, while the Rebotix EndoWrist Service Procedure mentions ultrasonic cleaning as one option for removing debris, it also offers the option to “clean with alcohol/acetone,”¹⁵² which in my experience would be inadequate to effectively remove debris.

90. Similarly, the process for removing the original PCB mounting clips requires removing an unspecified “small amount of material” from the PCB mounting pins.¹⁵³ When the pins are subsequently flattened by hammering and replaced on the pins to retain the Interceptor PCB, they will not have adequate holding force if too much material has been removed. This

¹⁴⁸ REBOTIX162404 at REBOTIX162420.

¹⁴⁹ REBOTIX175327.

¹⁵⁰ *See, e.g.*, REBOTIX133239 at REBOTIX133240 (dated Sept. 17, 2014); REBOTIX133272 at REBOTIX133273–74 (dated Sept. 17, 2014); REBOTIX133279 at REBOTIX133280 (dated Sept. 17, 2014).

¹⁵¹ *See generally*, REBOTIX162404.

¹⁵² *Id.* at REBOTIX162422

¹⁵³ *Id.* at REBOTIX162418.

could result in loose parts that interfere with operation of the cable drive components in the proximal housing, as well as generating debris that could fall into the surgical field or the patient.

91. Intuitive engineering documents describe this type of particulate contamination as a serious potential risk. For example, the 8mm instrument FMEA indicates that potential failures for various components within the proximal housing could result in “[p]arts or fragments fall[ing] into patient”; Intuitive assigns this risk a severity score of 9 out of 10 and requires mitigation by life testing.¹⁵⁴

92. I understand that Plaintiffs’ experts have opined that “EndoWrist failures during surgery” do not “put the patient’s safety at any risk,” and that instrument failures can be addressed by the surgeon during a procedure.¹⁵⁵ The contamination risks just described—e.g., debris falling into a patient—could occur without the surgeon noticing them and without the device itself becoming unusable. The presence of manmade materials within the body can trigger the well-known foreign body reaction, which is an inflammatory process that can lead to pain, adhesions, infections, and disruptions of normal physiological function.¹⁵⁶ Even microscopic debris (e.g., filaments from a broken cable) can lead to serious adverse responses in patients following surgery.¹⁵⁷

¹⁵⁴ See Intuitive-00538994 at Tabs 1, 2, and 11.

¹⁵⁵ See, e.g., Rubach Rep. ¶¶ 26–27.

¹⁵⁶ Anderson, James M., Analiz Rodriguez, and David T. Chang. “Foreign body reaction to biomaterials,” in *Seminars in Immunology*, vol. 20, no. 2, pp. 86-100, 2008; Wang, Cecily F., James Cipolla, Mark J. Seamon, David E. Lindsey, and S. Peter Stawicki. “Gastrointestinal complications related to retained surgical foreign bodies (RSFB): A concise review,” in *OPUS* 12:11-8, 2007.

¹⁵⁷ Truscott, Wava. “Impact of Microscopic Foreign Debris on Post-Surgical Complications,” in *Surgical Technol. Int’l*, vol. 12:34-46, 2004.

93. Furthermore, Rebotix was aware that this is a serious issue. Rebotix analyzed a “Risk Management Report Remanufactured EndoWrists” document, which reported EndoWrist failures in the FDA’s Manufacturer and User Facility Device Experience Database (MAUDE), as detailed in paragraph 109 below. This document recounted that the database analysis revealed 173 adverse events attributed to the da Vinci system, and approximately half involving debris falling into the patient, some of which were reported as injury to the patient (Figure 12).

- There were a total of 173 distinct MDR’s from all causes that could be attributed to the Da Vinci system. Based on careful review of each report, 13 of these events clearly led to patient injury that was potentially serious.
- Approximately half of the events involved debris falling into the surgical site. In all but 13 of these events, all debris was retrieved. In cases where some debris may have been left behind, the event was often still not reported as an injury to the patient.

*Figure 12.*¹⁵⁸

94. Another issue arises from the instructions in Rebotix’s service procedure regarding the tensioning of cables within instruments. While Intuitive uses specific tools (e.g., a tensioning tool and 40 in-oz torque driver as well as test fixtures for the instrument) to pre-tension cables to specific values to counteract the anticipated cable-stretch over the life of the instrument,¹⁵⁹ Rebotix uses a much less precise method. Rebotix instructs technicians to manually adjust the tension on the drive cables by “[u]sing the screwdriver turn the spool to apply tension to the cable,” noting that, “[o]nly enough tension to remove the slack from the cable is required.”¹⁶⁰ Rebotix also warns against “over tension[ing] the cable as this could create

¹⁵⁸ REBOTIX133038 at REBOTIX133040.

¹⁵⁹ *See supra* ¶ 47 (citing Intuitive-00537574 at Intuitive-00537575 and Intuitive-00705141 (Intuitive Manufacturing Process Instructions (MPI) Cable Tensioning, 838012); *see also* Nov. 8, 2022 Grant Duque (30(b)(1)) Tr. at 136:20–146:13.

¹⁶⁰ REBOTIX162404 at REBOTIX162422. This procedure is described in the “EndoWrist Service Procedure” document, which is dated January 25, 2019. Another document produced by Rebotix, dated five years earlier, identifies a different procedure for adjusting cable tension (“2014 Procedure”). *See generally* REBOTIX133344. It is unclear which procedure Rebotix actually uses to attempt to adjust cable tension, but both processes are flawed. In the 2014

problems during use.”¹⁶¹ The Rebotix Process, however, does not provide specifications or instructions for determining whether the cable is over-tensioned or under-tensioned. Nor did Rebotix have access to Intuitive’s original equipment specifications to know the appropriate level of tensioning.¹⁶²

95. This difference between Intuitive and Rebotix protocols has potential consequences to instrument reliability and patient safety. Improper tensioning of the instruments’ cables can lead to instrument failure, as observed in Intuitive life testing: under-tensioning can lead to derailments, while over-tensioning can contribute to cable wear and premature cable and bearing failure and increase friction in the drive system, which can reduce the range of motion and limit grip forces.¹⁶³ There is no indication in the EndoWrist Service Procedure that Rebotix understands the need to tension to a specific value to ensure that the instrument retains function over extended uses.¹⁶⁴

96. The prescribed visual inspection procedure (Step 5.2 of the “EndoWrist Service Procedure” and repeated in Step 7.2) is also inadequate to detect serious problems with an instrument. In general, the procedure provides only general instructions but does not explain what specifically should be checked. For example, in step 5.2.4 the procedure instructs the

Procedure, for example, the adjustment to the cable spool is apparently made by hand, while the operator’s other hand holds “modified dental pick” to re-spool the cable. *Id.* at REBOTIX133346.

¹⁶¹ REBOTIX162404 at REBOTIX162422.

¹⁶² June 22, 2021 Chris Gibson Tr. at 58:13–59:4.

¹⁶³ *See, e.g.*, Intuitive-00538913 at “2) IMA Backend Assy Processes” Rows 40, 41; Intuitive-00544494 at Intuitive-00544497. Rebotix also acknowledges problems can result from over tensioning, though it fails to acknowledge risks associated with under-tensioning. *See* REBOTIX162404 at REBOTIX162422.

¹⁶⁴ *See, e.g.*, Intuitive-00537574 at Intuitive-00537575 (“When each instrument is manufactured, the axis cables are tensioned to specific values. The tension ensures that the instrument remains functional throughout its lifetime as cable stretch occurs.”).

technician to “[v]erify that the manipulation wheels move freely in each direction throughout its full intended range of motion” but provides no guidance on what the full intended range of motion should be.¹⁶⁵ Moreover, only limited and inadequate inspection is required for components within the proximal housing, although the proximal housing contains numerous essential elements of the cable drive system that are exposed during servicing.¹⁶⁶ RMA results show failure modes that should be checked, including frayed cables within the proximal housing¹⁶⁷ and corrosion or contamination of the instrument bearings.¹⁶⁸ Finally, as noted above in section IV.B, even a thorough visual inspection is inadequate to detect serious deficiencies in the cable drive system.¹⁶⁹

97. In addition to the issues detailed above, there are numerous other problematic aspects of Rebotix’s servicing procedure. First, although electrostatic discharge is a well-known cause of failures in electronics manufacturing, the technician shown on Rebotix’s service video does not use electrostatic discharge (ESD) precautions when handling the Interceptor PCB.¹⁷⁰ Second, the Rebotix technician shown on the video uses compressed air from a hose to remove liquid from the instrument after ultrasonic cleaning.¹⁷¹ This appears to be “shop air” that is traditionally provided in labs and fabrication shops. Typically it is not filtered and often contains

¹⁶⁵ REBOTIX162404 at REBOTIX162413.

¹⁶⁶ REBOTIX162404 at REBOTIX162413.

¹⁶⁷ *See, e.g.*, Intuitive-695006 (RMA data) Tab 1 at Row 16798, 40346.

¹⁶⁸ *See, e.g.*, Intuitive-695006 (RMA data) Tab 1 at Row 173, 579.

¹⁶⁹ U.S. Navy Wire-Rope Handbook, Vol. 1, p. 3-15 (explaining that “[c]orrosion within a wire rope is almost impossible to detect visually, which makes it extremely difficult to determine the true condition of a corroded rope.”).

¹⁷⁰ REBOTIX175327. Although the SOP does address and attempt to account for ESD, the technician on the service procedure video does not appear to take any such precautions.

¹⁷¹ REBOTIX175327.

contaminants from the compressor and piping, and thus can introduce additional contamination to the instrument, both on the surface and in internal spaces that are problematic to clean. The Rebotix servicing procedure calls for use of “compressed air” to dry the instrument but gives no guidance or specification for its quality.¹⁷²

B. Rebotix’s Inadequate Risk Management and Life Testing

1. Rebotix’s Risk Management

98. Rebotix devised and executed a risk management process for its “remanufactured” instruments, including FMEA analysis and life testing. There are, however, a number of deficiencies in these procedures. In particular, the risk management process assumed that the Rebotix servicing procedure could restore instruments to a like-new state, ignoring the impact of the stresses that typical surgical use imparts to instruments and, as explained at length above, leads to failures. In addition, it appears that Rebotix’s risk management process gives little or no consideration to mechanical failures, although the importance of mechanical failures is clear from Intuitive’s risk management activities for EndoWrist instruments, as well as Rebotix’ own risk management documents.¹⁷³

99. In support of my analysis of Rebotix’s risk management practices, I reviewed the documentation identified by Rebotix as the “Rebotix Endowrist Risk management File” as

¹⁷² REBOTIX162404 at REBOTIX162422. By contrast, Intuitive’s reprocessing instructions refer specifically to “clean, dry air” when air is used to dry EndoWrist instruments after sterilization. *See, e.g.*, da Vinci S and Si Instrument Reprocessing Instructions for Automated Cleaning and Disinfection, at 36, https://manuals.intuitivesurgical.com/c/document_library/get_file?uuid=d237e175-3fce-3844-863e-37e733afe0d6&groupId=73750789; da Vinci Xi Instrument Reprocessing Instructions for Automated Cleaning and Disinfection, at 36, https://manuals.intuitivesurgical.com/c/document_library/get_file?uuid=b1b9f169-4503-9ea9-6db9-9243c28d5221&groupId=73750789. “Clean air” is a widely used term that refers to a specific quality of air that is higher than “shop air.”

¹⁷³ *See e.g.*, Intuitive-00538994 (8mm Instrument Family FMEA with various tabs devoted to potential mechanical failures).

part of the technical file review located at REBOTIX162889. The technical file review identifies the following six component parts of the “Rebotix Endowrist Risk management File”: (1) Risk Management Plan; (2) Design Failure Mode and Effects Analysis; (3) Risk Management Report; (4) IEC 60601 Risk Management Table; (5) Rebotix Endowrist MDR Report; and (6) Rebotix Endowrist MDR Sub Report.¹⁷⁴

100. The central assumption of Rebotix’s risk management for EndoWrist instruments is that their remanufacturing process restores instruments to like-new “OEM product” conditions. Thus, risks due to wear and tear from continued use beyond the originally programmed lives are not considered to be significant. This is described in the Rebotix “Risk Management Plan.”¹⁷⁵

Due to considerations that are unique to the situation of remanufacturing the EndoWrists, the following conventions will be adopted for the design FMEA:

- The baseline risks inherent in the OEM product will be estimated as “pre-mitigation” risks, and OEM risk controls will be identified.
- Actions, mitigations, or control measures will be implemented to ensure that risk levels for remanufactured EndoWrists do not exceed those that were estimated for the OEM device. Remanufacturing does not affect the design of the EndoWrists (except for modifications to the use count chip), so many of the risk controls will be process-based methods of restoring OEM design mitigations.
- In addition to the risk acceptability levels established below in Table C, any estimated hazard severity or probability of occurrence for the remanufactured EndoWrists that exceeds that estimated for the OEM Endowrists will be considered unacceptable.

101. This concept is reiterated throughout Rebotix’s “Risk Management Report.” For example:

It is presumed that all risks related to the OEM EndoWrists, as they are originally placed on the market, have been controlled to an acceptable level. As such, the risk management approach adopted was to analyze the known and potential hazards inherent in the OEM Endowrists, and then use appropriate risk controls to ensure

¹⁷⁴ See REBOTIX162889 at REBOTIX162901.

¹⁷⁵ REBOTIX123792 at REBOTIX123794.

that the probability of any resulting harms occurring is no higher in remanufactured Endowrists than it is in OEM Endowrists. Many of the controls employed by Rebotix will actually serve to restore design-based mitigations of the OEM devices, and will ultimately be process-based, by nature.¹⁷⁶

102. Rebotix ignored, however, the key Intuitive risk control measure of limiting the number of surgical uses and assumed that wear and tear that occurred after new instruments satisfied “OEM-equivalent specification” was negligible.

103. Also as part of its risk management analyses, Rebotix performed a design FMEA and identified a number of potential risks involving mechanical failures.¹⁷⁷ One example is the entry on line 26; under “Key process step or input” / “Potential Failure Mode” / “Potential failure Effect,” Rebotix lists “Cable torque shall allow for the 4 degrees of freedom (wrist pitch, wrist yaw, roll, and grip) / User unable to manipulate tool end as needed during a procedure (slack in cable) / Device performs poorly during procedure, Possible serious injury (surgical intervention required).”¹⁷⁸ Regarding this risk, for “Actions, mitigations, or control measures implemented”/ “Verification of risk control” Rebotix lists “Cable torque procedures and inspection PR3043, PR3050, PR3052” / “Simulated life testing (ALL - see note 1).” The referenced documents provide instructions on inspecting used instruments and setting the cable tensions.¹⁷⁹ None of the

¹⁷⁶ REBOTIX133038 at REBOTIX133039. *See also, e.g.*, REBOTIX133038 at REBOTIX133041 (“Consistent with the approach of restoring the remanufactured Endo Wrists to OEM-equivalent specification, the most common risk control utilized was to restore risk controls that were inherent in the OEM design.”).

¹⁷⁷ REBOTIX084174.

¹⁷⁸ REBOTIX084174 at REBOTIX084176.

¹⁷⁹ REBOTIX121303; REBOTIX123447; REBOTIX133344. Although these documents describe a quantitative cable tensioning procedure, the EndoWrist servicing procedure, REBOTIX162404, spells out a different, qualitative procedure: “Only enough tension to remove the slack from the cable is required. Do not over tension the cable as this could create problems during use.” REBOTIX162404 at REBOTIX162422.

listed “Actions, mitigations, or control measures implemented,” however, is adequate to restore an instrument that has been used in repeated surgical procedures to a state that is equivalent to OEM specifications for a new instrument. As noted above, during normal use of an EndoWrist instrument, drive cables may be damaged, bearings may be contaminated, and other faults may arise that are not visible under inspection. *See supra* § IV.B.

104. Rebotix’s treatment of many other risks in its FMEA suffers from a similar reliance on inadequate procedures and testing.¹⁸⁰ In addition, and as shown below, Rebotix life testing does not adequately simulate the forces and interactions in surgery, so these measures are inadequate to ensure reliability of remanufactured instruments.¹⁸¹

105. I also reviewed Rebotix’s “Interceptor Circuit Card Risk Analysis and Assessment,” which limits its analysis to the Interceptor circuit card itself and the procedure whereby the card is inserted and does not consider mechanical interactions of the instrument during surgery.¹⁸² Rebotix repeatedly and explicitly indicates that the analysis within refers only to the risks related to the installation and function of the interceptor chip. In section 1.2, the “Document overview,” Rebotix notes that “[t]his document assesses any potential additional patient or user risk that might be introduced by the Interceptor Circuit Card Assembly installed in EndoWrist® Instruments used by the da Vinci® Surgical System.”¹⁸³ Furthermore, in section 2.4, “Characteristics Affecting Safety,” Rebotix states:

Sub-clause 4.2 of ISO 14 971 requires the identification of those characteristics of medical devices that could affect safety. The following table of questions and answers are considered in the

¹⁸⁰ *See, e.g.*, REBOTIX084174 at REBOTIX084175-76 (Rows 17-34).

¹⁸¹ *See e.g.*, REBOTIX170053 at REBOTIX170128, REBOTIX170180, REBOTIX170235, REBOTIX170283 (discussed below at ¶ 119).

¹⁸² REBOTIX084679.

¹⁸³ REBOTIX084679 at REBOTIX084683.

context of use of the Interceptor Circuit Card Assembly. The first part of each answer addresses the question in context of the surgical system, and the second part of each answer is in the context of the Interceptor's role.¹⁸⁴

106. Then line C.2.22 of the ensuing table states¹⁸⁵

C.2.22	To what mechanical forces will the medical device be subjected?	Since the da Vinci® Surgical System acts as a computer assisted extension of the surgeon's instruments, the EndoWrist® will experience the same physical forces as those experienced by surgical implements. Endoscopic Instruments may include rigid endoscopes, blunt and sharp dissectors, scissors, scalpels, shears, forceps/pick-ups, needle holders, retractors, stabilizers, and accessories for manipulation of tissue. Due to its design and location within the EndoWrist® housing, the Interceptor Assembly will not be subjected, nor be impacted by, any of these mechanical forces.
--------	---	--

107. Similarly, section 2.6, "Risk Analysis and Evaluation," includes an FMEA analysis table which (referencing the life testing discussed below) considers potential failures of the Interceptor itself, but lacks any consideration of failures due to the mechanical interactions that will occur during surgical use of the serviced devices.¹⁸⁶ Thus, the report fails to consider the role of mechanical forces to which the serviced instruments will be subjected during their extended life.

108. The overall strategy of ignoring wear and tear and assuming that the remanufacturing process restores device specifications to an OEM-equivalent state is also explicitly stated in Rebotix's "IEC 60601 Risk Management Matrix."¹⁸⁷ This document

¹⁸⁴ REBOTIX084679 at REBOTIX084685.

¹⁸⁵ REBOTIX084679 at REBOTIX084688.

¹⁸⁶ REBOTIX084679 at REBOTIX084693.

¹⁸⁷ REBOTIX084240 at REBOTIX084242-45.

enumerates the Rebotix risk assessment for the remanufactured EndoWrists under the requirements of ISO standard IEC 60601, which is the “Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.”¹⁸⁸ The matrix provides entries for the 14 “clauses” (categories of requirements) of ISO standard IEC 60601.¹⁸⁹ Under “Justification for Exclusion or Description,” Rebotix states that it need not consider design-related risks: “The device design specifications and design-related risk management file resides with the OEM. The remanufacturing process restores device specifications to an OEM-equivalent state, and does not alter them.” This entry appears under 13 of the 14 clauses.¹⁹⁰ Again, this ignores the effects of continued usage.

109. Finally, it is clear that Rebotix was in possession of data and analyses that showed that mechanical failures represented a large portion of all failures observed in EndoWrist instruments, and that showed the increased risk of continued use of EndoWrist instruments beyond their originally specified number of uses. The “Risk Management Report”¹⁹¹ references reports Rebotix commissioned that analyze EndoWrist problems and failures through the FDA’s Manufacturer and User Facility Device Experience Database (MAUDE):

Since Rebotix did not have access to the OEM compliant files, an assessment of publicly-available complaint information was required in order to estimate the current probability of occurrence rates for OEM Endowrist failure modes. An exhaustive review and analysis of the FDA MAUDE database and other available sources of relevant information was performed and documented in the report, 420000-001 Rev 2 “Rebotix Endowrist MDR Report”.¹⁹²

¹⁸⁸ REBOTIX162889 at REBOTIX162903.

¹⁸⁹ REBOTIX084240 at REBOTIX084242-45.

¹⁹⁰ *Id.*

¹⁹¹ REBOTIX133038.

¹⁹² REBOTIX133038 at REBOTIX133039. The FDA website provides a description of MAUDE: “Manufacturer and User Facility Device Experience (MAUDE) database represents

110. The referenced report—the “Rebotix Endowrist MDR Report”¹⁹³ and the accompanying “Endowrist MAUDE Sub Report”¹⁹⁴—contain a detailed analysis of instrument issues reported to the FDA for 2007 to 2012. These analyses show that mechanical failures were among the most common issues, and that issues increased with the number of uses.

111. Numerous mechanical failures are reported throughout these documents. For example, page 8 of the Rebotix Endowrist MDR Report notes¹⁹⁵:

Broken and Foreign Bodies

The grouping of “Broken” consists of any mention of broken grips, broken wires, broken clevis, conductor caps, blades tips, etc., in either the Event Description or the Manufacturer’s Narrative. Almost half of all the MDR’s indicate something broken.

112. Similarly, a count of keywords in the descriptions of instrument failures for the ProGrasp Forceps showed that 17 of 52 observed issues involved the cable drives, e.g., “grip cable derailed at distal idler” and “pitch cable broken at distal clevis.”¹⁹⁶ The same pattern of a large fraction of the failure reports mentioning cable issues is observed for many of the instruments analyzed.

reports of adverse events involving medical devices. The searchable database contains the last 10 years of medical device report (MDR) data. MAUDE may not include reports made according to exemptions, variances, or alternative reporting requirements granted under 21 CFR 803.19. The downloadable data files consist of voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996. The public may search the database for information on medical devices that may have malfunctioned or caused a death or serious injury. Data for the past 10 years is available through the end of the previous month.” U.S. Food and Drug Admin., Manufacturer and user facility device experience database – (Maude), <https://www.fda.gov/medical-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities/manufacture-and-user-facility-device-experience-database-maude> (last visited Jan. 18, 2023).

¹⁹³ REBOTIX090153. MDR refers to FDA Medical Device Reporting, *see* <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

¹⁹⁴ REBOTIX089889.

¹⁹⁵ REBOTIX090153 at REBOTIX090160.

¹⁹⁶ REBOTIX090153 at REBOTIX090168.

113. Evidence that increased instrument problems correlated with increased instrument usage was identified in the MDR report.¹⁹⁷ This analysis “shows the returned Endowrists and how many lives were left.”¹⁹⁸ For instruments that started with 10 lives, the data shows that most of the failures (53%) occurred in instruments with 3 or fewer lives remaining, while only 19% of failures occurred in instruments with 7 or more lives remaining.¹⁹⁹ This data demonstrates to a statistically significant degree that instruments wear out and show increased failure rates with increased usage.

114. In summary, the Rebotix risk management approach is flawed. It assumes that EndoWrist instruments could be serviced to restore the same level of reliability as new instruments, and ignored the damage that occurs in normal surgical use of these instruments. This is evident throughout the pertinent Rebotix documentation, from the high-level Risk Management Plan and Report, to specific documents such as the FMEAs for the instruments and the Interceptor and the 60601 Risk Matrix. In addition, the risk management process failed to recognize the frequency of mechanical failures, even though reports they commissioned clearly showed the prevalence of such failures. This error was compounded in the Rebotix life testing described below, where the mechanical loading used was inadequate to simulate actual surgical conditions and thus failed to produce a realistic mechanical failure rate.

2. Rebotix’s Life Testing

115. Rebotix also purported to perform life testing on EndoWrist instruments in order to “demonstrate that [EndoWrist instruments] would consistently meet specified safety and

¹⁹⁷ REBOTIX090153 at REBOTIX090164.

¹⁹⁸ REBOTIX090153 at REBOTIX090164.

¹⁹⁹ *Id.*

performance requirements through the rigors of eleven simulated use cycles following re-manufacture.”²⁰⁰ However, as with Rebotix’s risk management procedures, there are numerous deficiencies in Rebotix’s life testing.

116. Rebotix’s selection of specific models for life testing was based on a purported worst case analysis.²⁰¹ Rebotix notes that, “[f]or the purpose of life testing, worst case means that no other Wrists represent a greater risk of failure.”²⁰²

117. Rebotix established worst case instruments by determining that: “1. Each Tool End Design (Scissors, Graspers, Needle Drivers, and Non-Operating Cautery) must be challenged. 2. Each Energized Wrist Type (Monopolar, Bipolar, and PK) as well as non-energized Wrist type must be challenged. 3. Each Part per the Part Index must be challenged.”²⁰³

118. These criteria do not include the role of forces in limiting instrument life. In contrast, Intuitive’s life test verification of EndoWrist instruments involves subjecting instruments to forces—similar to those encountered during surgery—that can and do limit instrument life.²⁰⁴ For example, as discussed in Section V.B above, Intuitive’s delta life test verification of the IS1200 and IS2000/IS3000 Mega SutureCut needle driver (MSCND) and Large SutureCut needle driver (LSCND) used animal tissue models to provide reaction forces (e.g., forces of approximately 2 lbs) simulating those forces produced in surgical procedures.²⁰⁵ In the case of the MSCND and LSCND instruments, one of the eight instruments tested failed on

²⁰⁰ REBOTIX170053 at REBOTIX170053.

²⁰¹ REBOTIX146770 at REBOTIX146771.

²⁰² REBOTIX146770 at REBOTIX146771.

²⁰³ REBOTIX146770 at REBOTIX146772.

²⁰⁴ See generally Intuitive-00544199; Intuitive-00544494.

²⁰⁵ Intuitive-00544199 at Intuitive-00544201.

the fourth test cycle due to a cable derailment.²⁰⁶ Moreover, Intuitive’s worst-case analysis for its instruments includes and accounts for mechanical forces, for example, Intuitive selects the instruments that have the highest design loads (defined as the “comparative ranking of the stress an instruments drivetrain components are subject to during use”) or the highest levels of cable tension as worst-case instruments.²⁰⁷

119. Rebotix’s life testing did include some interactions with chicken breast that were intended to simulate what the instruments would experience during actual surgical procedures. For example, to simulate the use of cautery instruments during surgery, the instruments applied a series of burns to chicken breast,²⁰⁸ and to simulate the grasping of tissue, the instruments grasped chicken breast.²⁰⁹ However, in none of the tests was significant force applied to the instruments, as would happen during an actual surgical procedure. This is in contrast to Intuitive life testing, where large forces are required to be applied to the instruments to simulate both tissue interactions and collisions or other interactions between instruments.²¹⁰ The greater forces applied to instruments by Intuitive during life testing, which more realistically simulate actual clinical use, increase the amount of wear and tear an instrument experiences during life testing.

120. Rebotix’s inadequate life testing also does not appear to include any statistical analysis, like Intuitive’s Weibull Design of Reliability analysis, to determine the number of instrument samples and use cycles that are required to statistically “prove” a number of instrument lives. This flaw is significant because, as discussed above, Weibull Distribution

²⁰⁶ Intuitive-00544494 at Intuitive-00544497.

²⁰⁷ Intuitive-00027876 at Intuitive-00027879-00027881.

²⁰⁸ REBOTIX170053 at REBOTIX170235.

²⁰⁹ REBOTIX170053 at REBOTIX170128; REBOTIX170180; and REBOTIX170283.

²¹⁰ Intuitive-00544199 at Intuitive-00544201 (noting that “2 lbs” of force applied in the MSCND and LSCND tests).

accounts for the potential for failures throughout a product’s useful life and supports reliable performance throughout that useful life.²¹¹ Instead, it appears Rebotix assumes that all S/Si instruments are reliable to a certain number of uses as long as the test instruments did not fail throughout that number of life cycles.²¹² Even if Rebotix’s life testing were adequate to simulate surgical uses (and it is not, for the reasons described above), Rebotix’s approach to life testing fails to account for potential failures throughout an instrument’s useful lives that might not be caught in life testing and also fails to build in any safety margin beyond the number of uses tested.

121. Rebotix claims it builds in a 20% safety margin to its life testing by adding 12 “exercises” beyond the 60 it deems necessary for a simulated use cycle for a total of 72 exercises.²¹³ “Exercises” are defined as the manipulations/activations that an instrument performs during surgery (e.g., moving through a range of motion, cutting and grasping).²¹⁴ However, this approach to building in a safety margin is flawed for at least two reasons: First, as described above, Rebotix life testing does not adequately replicate the forces exerted during surgical uses. Second, by opting for a longer surgical use cycle, rather than testing instruments for additional uses, Rebotix life testing excludes additional reprocessing cycles. Intuitive, by contrast, builds in a safety margin based on additional uses, which requires it to subject its life testing instruments to additional surgical use cycles *and* additional reprocessing cycles to build in a safety margin. Intuitive’s approach better approximates actual surgical use, which necessitates a reprocessing cycle to ensure the instrument is sterile before it is used on a patient.

²¹¹ See *supra* ¶ 67 (citing Intuitive-00477757, Intuitive-00477597; Intuitive-00477620).

²¹² REBOTIX170053.

²¹³ See REBOTIX170053 at REBOTIX170053.

²¹⁴ See *id.*

122. The deficiencies with Rebotix life testing are made even clearer when compared with the results Intuitive experienced during its life testing in conjunction with its Extended Use Program for certain X and Xi instruments. The Extended Use Program aimed to take advantage of diverse improvements in instrument design and reprocessing practices relevant to the X and Xi instruments to enable customers to use certain X and Xi instruments for more than the originally validated ten lives. The “White Paper, Extended Lives Supporting Materials” document provides details on the program and the life testing that provided the basis for life extension:

Da Vinci instruments, which are used in procedures and are reprocessed between uses, experience degradation throughout their lifetime. Instrument degradation can eventually lead to poor instrument performance or a device failure. To ensure reliability and reduce the possibility of instrument failures occurring during a procedure, the number of uses per instrument are limited. Fewer instrument lives increases confidence of adequate performance, but also results in additional customer cost by requiring more frequent replacement and purchasing. Based on a number of design and manufacturing improvements made over the past several years, as well as efforts to reduce reprocessing practices at hospitals, and in an effort to reduce costs for the customer, a number of X/Xi instruments have been re-evaluated for extended life reliability. The results of this testing have made it possible to increase certain instruments’ rated use and reprocessing life, while still ensuring safe and adequate performance throughout the instrument lifetime, with no impacts to our risk-based confidence and reliability requirements....

To analyze the ability of instrument lives to be extended safely, life testing was performed on X/Xi instruments and a cumulative risk analysis was completed and summarized. Life testing that was used previously to validate the specification of 10 lives (for most instruments) was completed “to failure” to determine the maximum allowable number of lives for each instrument, utilizing knowledge gained from years of instrument usage. Although each design change had its own risk analysis, a cumulative risk analysis was

completed to understand how risk is affected by all of the changes combined.²¹⁵

123. While the Extended Use Program was limited to certain da Vinci model X/Xi instruments, and found that certain X/Xi instruments are able to be used safely and reliably for a few more than ten uses, Intuitive's testing showed that none of the X/Xi instruments could reliably and safely be used for the number of times third parties claim they can safely reset S/Si instruments.²¹⁶ I would expect these findings to apply with equal or greater force to S/Si instruments. Intuitive made improvements to the X/Xi instruments over time such that certain of the X/Xi instruments may have a small number of reliable uses above 10, as Intuitive demonstrated as part of the Extended Lives Program. For example, Intuitive changed a number of components used in X/Xi instruments including the pitch cable, grip cable, and the grips.²¹⁷ Since those component changes were not made to S/Si instruments, there is no basis to assume that those instruments would perform reliably over more than 10 uses.

124. In Intuitive's Extended Use Program testing, twelve different X/Xi instrument models and a total of 250 instruments were tested. Life test protocols involving an initial reprocessing cycle, followed by interleaved surgical use cycles (SUCs) and reprocessing cycles, consistent with Intuitive's typical life testing protocols described above.²¹⁸ The instruments were put through 14 to 22 SUCs, and at least one instrument of every model suffered failures by SUC

²¹⁵ Intuitive-00004692 at Intuitive-00004692.

²¹⁶ Intuitive-00290857 at Intuitive-00290859; Oct. 27, 2022 Nickola Goodson Tr. at 222:13–20, 232:18–233:18, 233:19–24; Oct. 6, 2022 Disha Peswani Tr. at 106:8–17, 113:21–114:4, 114:9–18, 115:4–12, 156:2–9; Intuitive-00004692; Intuitive-00004685; Intuitive-00552529; Intuitive-00552530; Intuitive-00552535.

²¹⁷ Oct. 6, 2022 Disha Peswani Tr. at 116:2–13.

²¹⁸ See *supra* § V.B.

22. Further, a total of 70 failures were observed from the 250 units. 52 of those instruments failed as a result of cable drivetrain stretch/fatigue/yield.²¹⁹

125. Using Weibull analysis, Intuitive engineers showed that the extended life test results provided evidence that the instruments were reliable for between 12 and 18 uses. None of them were shown to meet reliability standards for the number of uses (19 or 29) that Rebotix claims to have verified.²²⁰

126. In contrast, Rebotix's life testing did not identify a single failure through 20 life cycles.²²¹ This stark difference in results cannot be explained by the differences between Intuitive's X/Xi and S/Si EndoWrist instruments and provides further evidence of the inadequacy of the Rebotix life test protocols to simulate surgical usage.

C. Rebotix's Summary of Quality and Reliability Measures and Technical File Review Do Not Support Any Safety and Reliability Claims.

127. I understand that Rebotix provided Restore what it described as "documentation showing results from independent regulatory testing that was completed."²²² The attached materials included (1) a file titled "EndoWrist Service Procedure Overview,"²²³ and (2) a "Technical File Review," which was performed by DQS MED.²²⁴ The Technical File Review

²¹⁹ Intuitive-00552535.

²²⁰ *See id.*; *see also e.g.*, Rebotix's Responses and Objections to Intuitive's Second Set of Interrogatories, at Interrogatory 3. I note that the spreadsheet summarizing Intuitive's extended life test results indicates that the ProGrasp instrument "Rated USE life Qualified" is 20 uses. *See* Intuitive-00552535. However, the original test document (862214-04R) and the Extended Lives White Paper both state that the verified number of uses is 18. *See* Intuitive-00551503; Intuitive-00004692.

²²¹ *See* REBOTIX170053.

²²² Restore-00060361.

²²³ Restore-00060362.

²²⁴ Restore-00060365.

included an assessment of Rebotix’s “Risk Management File” and simulated life testing, both of which were described above. *See supra* § VI.B.

128. I also understand that during the period Restore was utilizing the Interceptor to bypass Intuitive’s usage counter, [REDACTED]

[REDACTED]

[REDACTED]

129. The summary information provided in the DQS MED Technical File Review relied upon by Restore does not provide the type of validation required for the claims Restore made about the safety and reliability of reset EndoWrist instruments.²²⁶ For example, the Technical File Review provides only a brief summary drafted by Rebotix itself that its simulated use life-testing protocol verified certain requirements during and after a total of 10 additional uses. The Technical File Review provides little detail regarding Rebotix’s risk management and life testing activities. And, as described above, those risk management and life testing activities were themselves inadequate to support Rebotix’s safety and reliability claims.

130. I understand that the material provided to SIS by Rebotix on Rebotix’s risk management activities and testing was limited to the “Summary of Quality and Reliability

²²⁵ May 6, 2021 Kevin May Tr. at 129:3-130:21

²²⁶ *See* May 6, 2021 Kevin May Tr. at 41:10-50:4 (explaining that the DQS MED Technical File Review was the only written report of testing performed on EndoWrist instruments that Restore received from Rebotix, that other “summaries” of the DQS MED Technical File Review were provided that Restore relied upon, and that there was “additional information stating that [Rebotix] did some additional testing. But there was not a lot of details in that additional testing”).

Measures” document.²²⁷ SIS did no independent testing of the EndoWrist instrument reset process and instead relied on Rebotix’s testing.²²⁸

131. The Summary of Quality and Reliability Measures document does not demonstrate the safety and reliability of Rebotix’s resetting process, providing only a high-level listing of the processes, standards, and tests that were purportedly applied to the development of the Rebotix repair process. Insufficient information is provided to determine if the devices are actually safe and reliable. For example, the section titled “Risk Management” states that a “A detailed FMEA (Failure Modes and Effects Analysis) was performed covering the service process.”²²⁹ No information is provided about the process used to develop the FMEA, and if the process was inadequate or the FMEA was incomplete then the results do not establish a suitable level of safety or reliability.

132. Similarly, the “RELIABILITY/PERFORMANCE TEST SUMMARY” section states that new EndoWrist instruments were characterized to determine functional properties (*See* Figure 13), and then repaired instruments were subjected to formal life testing to establish reliability:

²²⁷ *See* Nov. 1, 2022 Greg Posdal 30(b)(6) Tr. at 25:7-25; *id.* at 27:15-20; Def.’s Ex. 136, SIS095115-095139 at SIS095126-095139.

²²⁸ Nov. 1, 2022 Greg Posdal 30(b)(6) Tr. at 22:24-23:2; *id.* at 23:23-24:1; *id.* at 25:1-6; *id.* at 29:6-11; *id.* at 30:8-13; *id.* at 32:4-6; *id.* at 49:23-50:3.

²²⁹ Def.’s Ex. 136, SIS095115-095139 at SIS095132.

Initially, a quantity of each representative model was characterized by their mechanical and functional properties. New OEM instruments were analyzed to provide baseline statistics and information. Examples of such statistics include, but were not limited to:

- Tool end range of motion
- Tool end functional performance (e.g. grasping performance and cutting performance)
- RF energy effectiveness
- Electrical safety testing
- General instrument condition
- Effective communication and use counting on the host system

*Figure 13.*²³⁰

Following the OEM characterization, instruments with one remaining use underwent the repair process. Immediately following the repair process, the instruments were subjected to the same baseline testing in order to establish equivalence. Formal life-testing was then conducted to simulate an additional 10 uses. The life testing subjected the instrument to 10 simulated surgical environments to test each aspect of the individual instrument's functional capabilities.²³¹

133. It is not possible to determine from the summary information provided what was included in the testing and evaluation. If the “simulated surgical environments” that were used to test the repaired instruments did not include realistic motions and loading typical of actual surgery, then the test results are inadequate to establish safety and reliability.

134. The same section of the document states “A worst-case analysis was carried out to determine which models should be used during performance and life testing.”²³² No information is provided about the criteria used to determine which instruments represent the “worst-case,” or even how “worst-case” is defined. The document does not state which set of instrument models were selected. Without such information, it is not possible to determine if the selection process was appropriate and effective.

²³⁰ *Id.* at SIS095137.

²³¹ *Id.*

²³² Def.’s Ex. 136, SIS095115-095139 at SIS095136.

135. The “RELIABILITY/PERFORMANCE TEST SUMMARY” section also states:

Following the formal testing described above, a smaller batch of representative models were subjected to over 50 cleaning and sterilization cycles to demonstrate the robust nature of the instrument's design. Similar inspection and testing was carried out on these devices, and, as expected, no indications of material degradation were observed.²³³

Here again, the document does not provide essential information to determine safety and reliability. The process used for “inspection and testing” is not explained in any detail, and it is not specified how “material degradation” was assessed.

136. The document also lists over two dozen industry standards, and states “The following list of standards was considered and applied to the development process...” and “Tests were conducted with devices serviced to demonstrate compliance to the following standards...”²³⁴ Once again, no information is provided about how these standards were “applied to the development process” or how the tests were conducted. Without this information, it is not possible to determine if they support an assessment of safety and reliability.

VII. Intuitive’s Efforts to Create a Refurbishment Program Do Not Prove the Safety or Reliability of EndoWrists Reset by Third Parties.

137. I understand that between 2016 and 2020, Intuitive considered starting an EndoWrist refurbishment program for X and Xi instruments.²³⁵ Plaintiffs’ experts appear to assume Intuitive’s consideration of such a refurbishment program constitutes evidence that third-party EndoWrist “reset” offerings are safe and reliable. I disagree.

138. Intuitive ultimately did not implement a refurbishment program because it would have needed to demonstrate the reliability of the refurbished instruments and it determined that

²³³ Def.’s Ex. 136, SIS095115-095139 at SIS095138.

²³⁴ Def.’s Ex. 136, SIS095115-095139 at SIS095132-135.

²³⁵ Oct. 27, 2022 Goodson Tr. at 70:11–72:20.

the cost associated with part replacements necessary to achieve that reliability became “cost prohibitive.”²³⁶ For example, Intuitive replaced the EndoWrist cables during its refurbished instrument testing process but still observed broken cables during life testing.²³⁷ In other words, Intuitive concluded that safely and reliably refurbishing EndoWrist instruments required replacing components of the instruments, not simply sharpening them and manually adjusting cables.

139. The outcome of Intuitive’s refurbishment project testing therefore actually supports my conclusion that the Rebotix process was inadequate, rather than suggesting that the third-party EndoWrist reset processes are safe and reliable.

VIII. The FDA’s Recent Clearance of the Iconocare Process Does Not Prove the Safety and Reliability of Other Resetting Processes.

A. The Iconocare Remanufacturing Process

140. Iconocare submitted a 510(k) premarket notification submission for the Iconocare Process on February 16, 2021.²³⁸ The submission included a number of supporting documents.²³⁹

141. Six months later, following numerous email communications and meetings,²⁴⁰ Iconocare formally supplemented its 510(k) application, providing additional data and information, as well as evidence of revisions to the Iconocare Process reflecting comments and

²³⁶ *Id.* at 73:6–13.

²³⁷ *See, e.g.*, Intuitive-00626429 at Intuitive-00626431–32.

²³⁸ Restore-00086907.

²³⁹ Restore-00086957–Restore-00087398.

²⁴⁰ *See, e.g.*, Restore-00095403.

concerns from the FDA.²⁴¹ Iconocare continued to provide additional information to the FDA over the following months.²⁴²

142. [REDACTED]

[REDACTED]

B. The Rebotix Process and Iconocare Process Are Materially Different.

143. It is my opinion that there are significant differences between the Rebotix Process for remanufacturing S/Si EndoWrist instruments and the Iconocare Process for remanufacturing the S/Si 8mm Monopolar Curved Scissor EndoWrist, and these differences are likely to have a material impact on instrument reliability and patient safety. Some examples are listed below.

144. The Iconocare Process and Rebotix Process use different methods for altering the use counter in the instrument. An overview of the Rebotix Process for circumventing the usage counter on EndoWrist instruments was provided above in Section IV.C.

²⁴¹ See Restore-00087401–Restore-00089708.

²⁴² See, e.g., Restore-00106446; Restore-00132582; Restore-00109056.

²⁴³ Restore-00099137.

²⁴⁴ [REDACTED]

145.

146.

147.

²⁴⁵ Restore-00089490 at Restore-00089495.

²⁴⁶ Restore-00089490 at Restore-00089495

²⁴⁷ *See* Restore-00089490 at Restore-00089495, –98.

²⁴⁸ Restore-00001538 at Restore-00001562; Restore-00089490 at Restore-00089495 (Iconocare Process pt. 7.3.5.1.8).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

148. While each of these steps will generate particulate debris, methods for thoroughly removing this debris are not provided in the Rebotix Process.²⁵²

149. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

²⁴⁹ Restore-00001538 at Restore-00001565; Restore-00089490 at Restore-00089495 (Iconocare Process pt. 7.3.5.2.2).

²⁵⁰ Restore-00001538 at Restore-00001565; Restore-00089490 at Restore-00089495 (Iconocare Process pt. 7.3.5.2.3).

²⁵¹ Restore-00001538 at Restore-00001565; Restore-00089490 at Restore-00089496 (Iconocare Process pt. 7.3.5.3.2).

²⁵² *Supra* § VI.A.

²⁵³ Restore-00089490 at Restore-00089497–98.

²⁵⁴ *Id.*



²⁵⁵ Restore-00089490 at Restore-00089497.

²⁵⁶ Restore-00089490 at Restore-00089497–98

150. [REDACTED]

[REDACTED] Corrosion is a particularly significant issue for EndoWrist Instruments. As explained in Section IV.B above, “The corrosion that results from reprocessing is well-known to degrade wire rope drives.”²⁵⁸ Corrosion accelerates wire-rope deterioration by reducing rope metallic area, limiting flexibility, and creating uneven wire surfaces that may cause internal damage to the rope and other equipment.²⁵⁹ While not all corrosion is externally visible in these instruments, inspection can detect external signs of degradation and serves to enhance instrument safety. The Rebotix Process, by comparison, has an insufficient visual inspection.²⁶⁰

151. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

²⁵⁷ Restore-00089490 at Restore-00089493.

²⁵⁸ Expert Report ¶ 34.

²⁵⁹ *Id.* (quoting U.S. Navy Wire-Rope Handbook, Vol. 1, p. 3-15).

²⁶⁰ *See, e.g.*, REBOTIX162404 at REBOTIX162413; REBOTIX162421–22.

²⁶¹ Restore-00089490 at Restore-00089492.



152.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Thorough documentation is essential for ensuring safety and reliability of medical device manufacturing practices.²⁶⁵

C. The Rebotix Process and Iconocare Process are Supported by Materially Different Risk Management and Life Testing Data.

153. It is my opinion that there are significant differences between the risk management and life testing data Rebotix had access to in connection with the Rebotix Process

²⁶² Restore-00089490 at Restore-00089492.

²⁶³ Restore-00089490 at Restore-00089490.

²⁶⁴ *Id.* at Restore-00089491.

²⁶⁵ See 21 C.F.R. §§ 820.180 *et seq.*; ISO 13485:2016 § 4.2.

and the risk management and life data submitted to the FDA for the Iconocare Process. Some examples are listed below.

154. In its 510(k) filing with the FDA, Iconocare describes a risk management process that refers to industry and regulatory standards. For example, the 510(k) application states that Iconocare followed a number of standards that prescribe methods for ensuring medical device safety and reliability, including:

- ISO 14971 (2d ed.): Medical devices – Application of risk management to medical devices;
- ISO 10993-1 (5th ed.): Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process; and
- AAMI TIR30: A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.²⁶⁶

Indeed, Iconocare’s 510(k) application reflects that the FDA asked various follow-up questions regarding Iconocare’s compliance with these standards, and that in response Iconocare submitted additional test reports.²⁶⁷

155. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

²⁶⁶ Restore-00086907 at Restore-00086909–10.

²⁶⁷ *See, e.g.*, Restore-00087401 at Restore-00087464.

²⁶⁸ Restore-00086907 at Restore-00086912.

[REDACTED]

156. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

²⁶⁹ Restore-00086907 at Restore-00086912.

²⁷⁰ Restore-00087861.

²⁷¹ *Id.* at Restore-00087868–69.

²⁷² EEPROM stands for electronically erasable programmable read-only memory.

²⁷³ Restore-00087861 at Restore-00087869.



157.

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

158. Such testing provides quantitative information for assessing the reliability of the remanufactured instruments, which is absent from the limited information available in connection with the Rebotix Process.

²⁷⁴ Restore-00087861 at Restore-00087869

²⁷⁵ Restore-00086959.

²⁷⁶ *Id.* at Restore-00086965.

D. Significantly Greater Safety Risks Are Created by Resetting an EndoWrist Usage Counter Multiple Times.

159. Plaintiffs’ experts have claimed that “EndoWrists can potentially be repaired multiple times”—using “repair” to apparently mean “reset.”²⁷⁷ I am not aware of any support for that claim. As discussed above (*supra* § VI.B), Rebotix’s inadequate and flawed life testing only tested EndoWrists through 20 life cycles. While *Restore* has claimed that EndoWrists could be reset anywhere from once to eight times, it has never had any evidence supporting that claim. To the contrary, and as also discussed above (*supra* § VI.C), the only testing documentation *Restore* ever had access to was a “Technical File Review” offering a brief summary of Rebotix’s life testing that only encompassed one reset.

160. Further, the Iconocare Process permits only a single remanufacturing cycle for S/Si 8mm Monopolar Curved Scissor EndoWrists by excluding previously remanufactured instruments from eligibility for further remanufacturing.²⁷⁸ As a result, no more than ten additional reuse cycles (for up to 19 total) are ever added to an instrument remanufactured through the Iconocare Process.²⁷⁹

161. It is my opinion that resetting an instrument’s usage counter multiple times, as the *Restore* Process contemplated, has a significantly greater impact on instrument reliability and patient safety than resetting an instrument’s usage counter just once under the Iconocare Process.

²⁷⁷ Elhauge Rep. ¶ 302, fn. 713.

²⁷⁸ See *Restore*-00090136 at -162–63 (“7.2.4.1. Unrepairable Items: Any model (or instrument version) not on the Approved Model List or in the Recall List are not eligible for repair. Previously refurbished instruments are not eligible for repair. All ineligible repairs are moved to a quarantine area pending disposition by management.”); see also *Restore*-00087134.

²⁷⁹ *Restore*-00089490 at *Restore*-00089492–93 (“If the Current Available Uses on an instrument is less than 1, the PCB will not be able to be installed and the instrument must be set aside for disposition. If the Current Available uses on an OEM instrument is greater than (or equal to) 1, the instrument can proceed with service process.”)

162. As explained above, data and analyses show that mechanical failures represent a large portion of all failures observed in EndoWrist instruments, and that continued use of EndoWrists beyond their originally specified number of uses increases the risk of instrument failure.²⁸⁰

163. The data demonstrates that instruments wear out and show increased failure rates with increased usage.²⁸¹ For example, the Rebotix EndoWrist MDR Report notes that almost half of all MDRs indicate something broken, including broken grips, wires, clevis, conductor caps, and blade tips.²⁸² For one instrument, 17 of 52 observed instrument failures involved the cable drives, e.g., “grip cable derailed at distal idler” and “pitch cable broken at distal clevis.”²⁸³ The same pattern of a large fraction of the failure reports mentioning cable issues is observed for many of the instruments analyzed.²⁸⁴ More of these failures are observed in instruments that are later in their original ten-use life cycle than those at the beginning of that cycle.²⁸⁵

164. The above evidence shows that EndoWrist instrument failure rates increase with the number of procedures where they are used. This implies that the reliability of these instruments will continue to decrease as they are remanufactured for use beyond 20 lives.

IX. Comparison of Intuitive’s da Vinci System Service, Maintenance, and Repair Procedures with Restore’s da Vinci System “Service” Offering

165. I understand that Plaintiffs allege that they should be permitted to use third parties to service their da Vinci surgical systems themselves, in addition to their desire to

²⁸⁰ *Supra*, ¶¶ 109–113.

²⁸¹ *Supra*, ¶ 113.

²⁸² *Supra*, ¶¶ 111–111.

²⁸³ *Id.*

²⁸⁴ *Id.*

²⁸⁵ *Supra*, ¶ 113.

purchase remanufactured EndoWrists.²⁸⁶ It is my understanding that neither Rebotix nor SIS has ever offered such services, but that Restore has. I have assessed both Intuitive’s system service, maintenance, and repair procedures and Restore’s system “service” offering, and conclude that Restore’s offering is deficient in numerous respects.

A. Intuitive’s da Vinci System Service, Maintenance, and Repair Procedures

166. As stated above, Intuitive manufactures and sells a minimally invasive robotic system called the da Vinci surgical system. Intuitive has developed detailed procedures for the service, maintenance, and repair of da Vinci systems. It is my understanding that Intuitive has developed proprietary software, which is stored on service laptops issued to field service engineers (“FSEs”). This software must be used to perform numerous critical maintenance and repair tasks on da Vinci systems, particularly critical tests and calibrations. The software also contains explanations for numeric “error codes.”²⁸⁷

167. Intuitive’s da Vinci service includes both preventative maintenance and repairs to the system (excluding da Vinci instruments, which are not repaired, but expire when they reach their validated usage limits). Preventative maintenance entails periodic maintenance performed by FSEs using a detailed series of checks to ensure the da Vinci system is functioning properly. Preventative maintenance is also designed to preemptively identify problems with the da Vinci system that may need to be addressed before they could possibly impact a surgery. Repairs are conducted in response to problems with the system (e.g., damaged or worn parts, calibration issues, unintuitive system motion) identified through a preventative maintenance

²⁸⁶ See, e.g., Hospital Compl. ¶¶ 3, 6.

²⁸⁷ See, e.g., May 13, 2021 West Gordon Tr. at 43:11-47:12 (explaining purpose and uses of software contained on Intuitive’s field engineer laptop).

event or reported by a customer outside of a regularly-scheduled preventative maintenance.

Further details on those procedures are included below.

1. Preventative Maintenance

168. As mentioned above, preventative maintenance is a detailed process for evaluating the da Vinci system and ensuring it remains fully operational. This process is memorialized in written procedures, which have been developed over time by Intuitive based on its knowledge of and expertise with the da Vinci system. Intuitive's preventative maintenance procedures ensure functional integration and calibration for the da Vinci system and also identify numerous errors that cannot be observed via a visual inspection of the da Vinci system. An overview of Intuitive's preventative maintenance process for IS3000 (Si) da Vinci systems is included below as Figure 20:

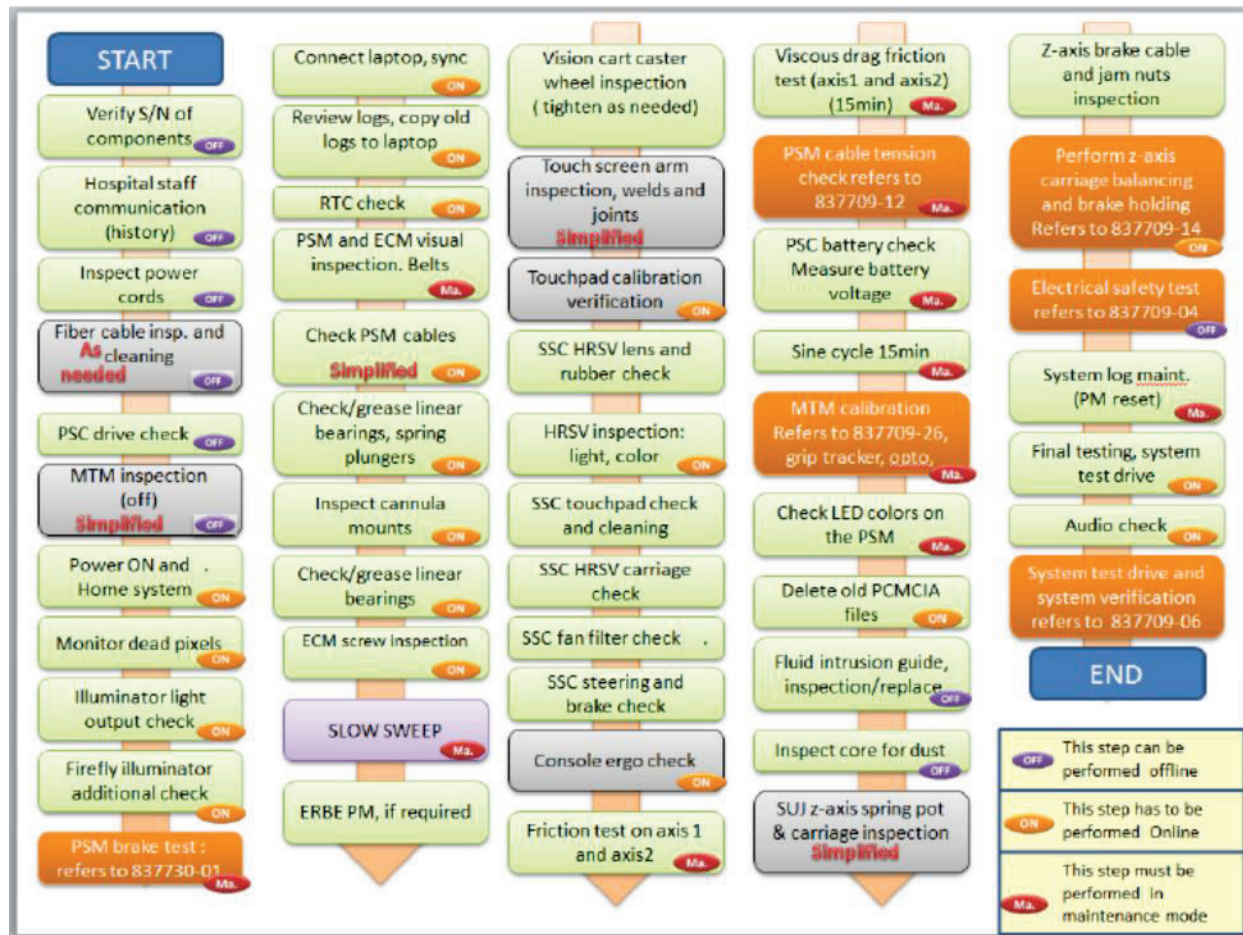


Figure 20.²⁸⁸

169. The IS3000 Preventative Maintenance document contains detailed instructions, complete with diagrams, on how to perform each step in the maintenance process. Although certain steps in the preventative maintenance process can be performed using visual checks and inspections (e.g., cord and cable inspections, monitor and illuminator checks, core inspection for dust accumulation),²⁸⁹ there are many critical steps that must be performed using Intuitive's software. Intuitive's software allows for precise measurement of critical components within the da Vinci system. The software is used to measure and detect issues with the systems' monitoring,

²⁸⁸ Intuitive-00705351 at Intuitive-00705357.

²⁸⁹ Intuitive-00705351 at Intuitive-00705359, Intuitive-00705361-62, Intuitive-00705390.

actuation, control, and electronics components. If these issues are not detected through preventative maintenance, continued operation of the system may create risk to the patient during a surgical procedure. Among other things, the system may move in jerky or non-intuitive ways, batteries may not function properly in the event of a power outage or instruments may not properly grasp or retract patient tissue. All of these issues can cause harm to a patient during a surgical procedure.²⁹⁰ In internal documents, Intuitive typically indicates that this proprietary software must be used by directing FSEs to select and launch “Compiled Matlab” or open the “MaintenanceApp” or “ServiceShell.” Some of the critical steps, including those requiring proprietary software, are detailed below:

170. **Review of Error Logs.** During preventative maintenance, FSEs must review the da Vinci system’s error logs.²⁹¹ Error logs from the most recent time period, known as “pop-up error logs” can be viewed while the da Vinci is in “normal mode” from the Vision Side Cart (“VSC”) touch screen or the Surgeon Side Console (“SSC”) touch-pad.²⁹² However, older logs must be accessed using the service laptop and proprietary software, which can put the system in “maintenance mode.”²⁹³ Connecting the laptop and running the MaintenanceApp allows FSEs to

²⁹⁰ Interview with Ron Bair, August 19, 2021.

²⁹¹ Intuitive-00705351 at Intuitive-00705363.

²⁹² Intuitive-00705253 at Intuitive-00705265; *see also* May 13, 2021 West Gordon Tr. at 54:18-55:15 (“Q. Was there any way to get the error logs other than by using the F.E. laptop? A. Yes. You could look them up on the Vision tower on that test screen monitor. You can go into the actual history and scroll through it, as well as the surgeon console. You can look through the surgeon console and go through the error logs that way as well. Q. And how – for how long did the Vision tower store the error codes? A. Not too long. I’m not sure. . . . [I]t just depends on how many errors there were and how often they use the system. Q. And is the same true of the surgeon console, that the error codes weren’t contained – or weren’t maintained for too long? A. That’s correct. Q. And what about the error logs that you could access with the laptop, was there – were there more available? A. Yeah. Indefinite.”); *id.* at 55:17-56:12 (explaining that although a PM would be performed every six months, only about a week of error logs were available without using the F.E. laptop).

²⁹³ Intuitive-00705253 at Intuitive-00705267-68.

review the system’s entire set of error logs.²⁹⁴ In addition, the MaintenanceApp allows FSEs to highlight numeric error codes, which do not contain a description of the specific error at issue, and pull up detailed descriptions of the error that can help FSEs troubleshoot a given problem, if needed.²⁹⁵ The service laptop also automatically uploads and stores error logs from the da Vinci system and allows FSEs to access and review prior error logs from that same da Vinci machine that have been uploaded.²⁹⁶

171. **Full Diagnostics.** Intuitive also instructs FSEs to run “full diagnostics” on each da Vinci system during Preventative Maintenance. This process is performed using the service laptop and running a MATLAB application referred to as “ServiceShell.”²⁹⁷ This full diagnostics process provides inputs that, among other things, factor into both the Patient Side Manipulator (“PSM”) and Endoscopic Camera Manipulator (“ECM”) Inspection and the Battery Check and Sine Cycle preventative maintenance procedures.²⁹⁸ Full diagnostics can only be performed using Intuitive software.

172. **PSM Slow Sweep Friction Test.** The Slow Sweep Friction test (“Slow Sweep test”) “measure[s] friction throughout the range of motion of Axis 1 and Axis 2 on PSMs.”²⁹⁹ The Slow Sweep also measures brake release voltage.³⁰⁰ The Slow Sweep test was developed by Intuitive to address a specific failure mode reported by customers. The failure mode caused jerky

²⁹⁴ *Id.* at Intuitive-00705267-70.

²⁹⁵ *Id.* at Intuitive-00705267.

²⁹⁶ *Id.* at Intuitive-00705269-73.

²⁹⁷ Intuitive-00705351 at Intuitive-00705365.

²⁹⁸ *Id.* at Intuitive-00705366, Intuitive-00705383-86.

²⁹⁹ Intuitive-00705438 at Intuitive-00705438.

³⁰⁰ *See id.* at Intuitive-00705447.

or non-intuitive motion.³⁰¹ As the name indicates, the Slow Sweep test generates extremely slow motion that can help identify damaged gear teeth or other causes of non-smooth motion that can be difficult to identify through maintenance tests that use faster trajectories.³⁰² Both parts of the slow sweep test must be performed using proprietary software.³⁰³ Further, depending on the friction and voltage values generated, the FSE may need to replace the entire PSM or the PSM Brake Gear.³⁰⁴ The specific steps taken in the Slow Sweep test are included below as Figure 21:

³⁰¹ Interview with Ron Bair, August 19, 2021.

³⁰² *Id.*

³⁰³ *See* May 13, 2021 West Gordon Tr. at 204:9-205:4 (explaining that the PSM friction test of the Intuitive Preventative Maintenance procedures could not be done without Intuitive's MATLAB software).

³⁰⁴ Intuitive-00705438 at Intuitive-00705450.



*Figure 21.*³⁰⁵

173. **PSM Cable Tension Checks.** PSM Cable Tension measurement checks are also performed using MATLAB software.³⁰⁶ Proper cable tension is essential to avoiding slippage within the PSM pulley system, which helps direct EndoWrist instruments. Without proper cable

³⁰⁵ Intuitive-00705438 at Intuitive-00705441.

³⁰⁶ Intuitive-00705143 at Intuitive-00705145-146.

tension, instruments may not move in the same way throughout a surgical procedure.³⁰⁷

Intuitive’s software plays an essential role in ensuring cable tension remains within Intuitive’s specifications. In particular, the software ensures that the arms are positioned correctly to reduce gravitational load and to turn off da Vinci servo drives (a type of motor in the cable tension system).³⁰⁸ If cable tension is measured without using Intuitive software, “the measurement will be *incorrect* and [the FSE] will *not be able to correctly adjust the tensions*.”³⁰⁹

174. **PSM Brake Test.** FSEs also perform a brake holding test on the PSM. It consists of [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

175. **Battery Check and Sine Cycle.** FSEs will check da Vinci system batteries and complete a “sine cycle” during a single step in preventative maintenance process. Portions of both the battery check and the entire sine cycle must be performed using the service laptop and proprietary software. Intuitive’s preventative maintenance process requires that FSEs use

³⁰⁷ Interview with Ron Bair, August 19, 2021.

³⁰⁸ Intuitive-00705143 at Intuitive-00705146.

³⁰⁹ *Id.* (italics in original).

³¹⁰ Intuitive-00705431 at Intuitive-00705431, Intuitive-00705433.

³¹¹ *Id.* at Intuitive-00705434, Intuitive-00705435.

Intuitive software to measure battery temperature and voltage to determine that the voltage remains within allowable limits while the system is operating on battery power.³¹² Batteries must perform within certain voltage ranges in order to ensure the battery can generate the backup power needed to operate the robot in the event of a non-battery power failure. If non-battery power fails, battery power is necessary to power the da Vinci system either through the completion of a surgical procedure or to allow for release of the da Vinci system's brakes so that the system can be removed from the patient in order to convert an ongoing procedure to a different type of surgery.³¹³

176. Similarly, the sine cycle conducts wide sweeping movement of the da Vinci system to detect non-intuitive motion. (The sine cycle is similar to the Slow Sweep test but is conducted at faster speeds with wider sweeping motions).³¹⁴ The sine cycle identifies potential problems with robot axes and, if problems are identified, may require replacement of da Vinci manipulators.³¹⁵

177. **Master Tool Manipulator ("MTM") calibration verification.** FSEs must also verify that the MTM is properly calibrated, and if not, perform any needed calibrations using the service laptop and MATLAB software.³¹⁶ Grips must be tested in their open, bumper, and closed

³¹² Intuitive-00705351 at Intuitive-00705381-82. Intuitive-00705384-85. *See also* May 13, 2021 West Gordon Tr. at 57:15-17 ("Q. Okay. Which of the things that you just described relied on the service laptop? A. Sign [*sic*] cycle and testing the arms movements.").

³¹³ Interview with Ron Bair, August 19, 2021. *See also* May 13, 2021 West Gordon Tr. 221:22-222:9 ("Q. And if the -- if it's being used in a surgery and the battery fails, is that a problem? A. Oh, absolutely. Yes. Q. Why is that? A. It could release power to the arms, allowing them to drop and allowing arm movement during the surgery. Q. And what would be wrong with that? A. I mean, it could move the arms. And if you're in the middle of doing something, you could lose control of them. Q. And that would impact the patient safety? A. It could, yes.").

³¹⁴ Interview with Ron Bair, August 19, 2021.

³¹⁵ Intuitive-00705351 at Intuitive-00705383-84.

³¹⁶ *Id.* at Intuitive-00705387-88.

positions to ensure they fall within acceptable values.³¹⁷ Similarly, the FSE must slide the roll axis buttons in order to generate a measurement that the open and trigger positions fall within acceptable values.³¹⁸ If any value fails, FSEs must re-calibrate the da Vinci system to ensure reliable functioning during a surgery.³¹⁹

2. Repair/replacement of damaged parts

178. In addition to Preventative Maintenance, Intuitive repairs and/or replaces damaged parts or components of the da Vinci system. Replacement parts cannot simply be inserted into the da Vinci system and work properly with the other existing components of the system. In most circumstances, new parts will be installed by FSEs and then calibrated and programmed to work with the hospital's system using Intuitive's software. Unless the new part is properly calibrated and integrated with the da Vinci system, the system will not accept the new part and it cannot be used.³²⁰

179. For example, if a PSM or an ECM is replaced, software must be used to sync the new part to the existing system's specific configuration and to program the new part with any necessary code.³²¹ Calibration may also be needed to make sure LED lights properly match the colors of LEDs on the new robot arms.³²² "Slave (PSM/ECM) calibration," while not normally required, must be performed in certain limited circumstances.³²³ Similarly, replacements to

³¹⁷ *Id.* at Intuitive-00705387.

³¹⁸ *Id.* at Intuitive-00705388.

³¹⁹ *Id.*

³²⁰ Interview with Ron Bair, August 19, 2021.

³²¹ Intuitive-00705406 at Intuitive-00705414-17.

³²² *Id.* at Intuitive-00705414; Intuitive-00705418-21.

³²³ *Id.* at Intuitive-00705422-30.

brakes, potentiometers (“pots”), and setup joints (“SUJs”) often must also be properly verified with the system, tested, and calibrated.³²⁴

180. Finally, Intuitive has specific procedures for battery box replacement on da Vinci systems. As mentioned above, the battery is essential to ensure that the da Vinci system will continue to work in the event of a non-battery power outage. Intuitive does not have any procedure for the repair of a battery component. The battery box is a third party component that Intuitive replaces by removing the current battery box and replacing it with a new battery box.³²⁵ The battery box is sealed to avoid tampering and ensure that the third party manufacturer’s calibration remains intact. If the seal on the battery is broken, Intuitive cannot be certain that the battery is properly calibrated or that its voltage can be properly read by Intuitive’s software.³²⁶

B. Restore’s da Vinci System “Service” Offering

1. Overview of Restore’s da Vinci “Service”

181. It is my understanding that Restore has held itself out to customers as offering da Vinci System “service,” for the da Vinci S and Si (otherwise known as IS2000 and IS3000) systems. It is also my understanding that Restore has never offered any type of service for X/Xi systems. I also understand that Restore has, at times, offered to customers two different types of “service” programs: A “PM Only” program and/or a “Spot Repairs” program.³²⁷

182. Restore described its PM Only program in a December 2018 document prepared for Panama City Surgical Center. Restore claimed the PM Only Program “provid[es] the

³²⁴ See Intuitive-00705453.

³²⁵ Intuitive-00705155 at Intuitive-00705173-76.

³²⁶ See Intuitive-00008958 (discussing the potential for calibration failure when a battery seal is broken).

³²⁷ See, e.g., Restore-00002095.

confidence and certainty of knowing that the surgical robot remains within ‘spec.’”³²⁸ Exhibit A to the PM Program Proposal, included below as Figure 22, identifies the “standard steps performed in [Restore’s] Preventative Maintenance Program.” Exhibit A to Restore’s PM Only Agreement omits many essential steps and lacks detail about the way measurements and functionality are tested.

³²⁸ See Restore-00002087 at Restore-00002087.



EXHIBIT A

The following are the standard steps performed in a Preventative Maintenance Program. Depending on the facility design and the Robot Model further steps may be added.

- I) **Perform Overall Physical Inspection**
 - Look for physical damage, bent connections, kinked or bent cables, damage to the housing units of the system (If there is physical damage, notate it and inspect the damage to determine if this will hinder any motion, rotation or electrical implications. If any of the following is true then determine the impact on the system and what it will take to fix the problem discovered)
- II) **As needed perform ground fault test on all 3 units separately**
- III) **Perform Joint manipulations (exercising the brakes and joints)**
 - Exercised each PSM (3 or 4 arm depending on system)
 - Take each PSM to its full extension (without instruments) and exercise each SUJ 270° or to its full extension in both directions several (2-3 times).
 - Blow out all boards and Cart electronics (using compressed air (non-chemical), fans, connectors and housings units of dust and debris
 - Checked all ESSJ internal connections on all SUJs PSM to PSC and PSC to PSMs
 - Checked all connection on top of PSC down through stack (Pot to Encoder), ESSJ connections, SUJ connections, etc.
 - Checked neutral & drive functionality as well as battery power and charge functionality (of PSC) (brake and trocar/cannula test functionality – safety feature)
 - Cycle MSD boards several times per board, blow out Surgeons consoles chassis
- IV) **Measurements and functionality**
 - Measure gram tensions per specifications on each PSM and record (see spec. sheet)
 - Check and test all degrees of freedom of the camera arm using force-feedback
 - Check and test all degrees of freedom of each PSM using force-feedback
 - Check and test all degrees of freedom of MTMs using force-feedback
 - Check and test all functionality of camera and camera ETM controllers (focus, rotation using MTMs, inward pitch, Yaw, all DOFs)
 - Check and test all functionality of Illuminator and bifurcated cable (Lumens if possible, need lumens/light reader)
 - Check time/hours usage of Illuminator (Under 500)
 - Check and test all functionality of focus controller both manually and robotically
 - Check and test all battery functionality on PSC
 - Check and cycle all board in Surgeon's console (IOD, PSD, MTM, etc.)
 - Final homing, driving and testing complete functionality of entire system as a whole with instruments, endoscope, cannulas, camera, vision tower and complete system

Prepare report of all issues found (if any) and preliminary plan for issue resolution.

Corp. Ofc. - 1275 Buford Hwy Ste 109 Suwanee Ga 30024

Repair Center - 6822 22nd Ave. North Suite 283 St. Petersburg FL 33710

WWW.RestoreRobotics.Com

678-400-0640



Figure 22.³²⁹

³²⁹ Restore-00002087 at Restore-00002089.

183. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

³³⁰ Restore-00025717 (Restore IS3000 Preventative Maintenance, Results Sheet).

³³¹ *See id.*; *see also* May 13, 2021 West Gordon Tr. at 189:23-190:7 (confirming Bruce McDaniel worked at Intuitive prior to employment at Restore); May 4, 2021 Clif Parker Tr. at 244:24-245:9 (“Q. Now Mr. McDaniel formerly worked at Intuitive. Is that so? A. Yes. . . . Q. Did he work for you or your companies for a period of time? A. For a very short period of time, he worked for one of our companies. Yes. Q. Who did he work for? A. Restore Robotics Repairs.”).

³³² *Compare* Intuitive-00705351 with Restore-00025717 (Restore IS3000 Preventative Maintenance, Results Sheet).

³³³ *Compare* Restore-00026026; Restore-00026027 (Version of Intuitive’s IS2000 Preventative Maintenance Results Sheet sent to Restore by Bruce McDaniel) *with* Restore-00025717 (Restore IS3000 Preventative Maintenance Results Sheet); *see also* May 13, 2021 West Gordon Tr. at 201:20-25 (“Q. And does this look like a preventative maintenance sheet for the IS2000 that you would have used when you worked at Intuitive? A. Not one that I’m familiar with. Mine look very different. But it does appear to be a P.M form from [Intuitive].”). West Gordon also confirmed that he used an Intuitive PM form while working at Restore. *See id.* at 212:12-24 (“Q. And you performed this preventative maintenance using an Intuitive P.M. form; is that right? A. I used it to log the results numbers that I got from it.”).

³³⁴ *See* Restore-00025717 (Restore IS3000 Preventative Maintenance, Results Sheet).

184. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

2. Restore's Technological Limitations Prevent It from Providing Adequate Preventative Maintenance or Repair of da Vinci Systems

185. As mentioned above, there are deficiencies in Restore's attempts to service da Vinci systems – either through preventative maintenance or repair. Restore admittedly has not developed any of its own software to service the system.³³⁷ As a result, Restore lacks the capacity to (1) conduct complete preventative maintenance and (2) repair most, if not all, components of the da Vinci system.

186. Restore itself acknowledges these limitations, even though it held itself out to customers as offering da Vinci service. In its Complaint, Restore conceded that “[b]ecause Restore does not have access to Intuitive’s ‘distributor’s toolkit’ it lacks ‘necessary documentation, software, and passwords to service da Vinci systems.’”³³⁸ Restore further conceded that it cannot:

³³⁵ See, e.g., Restore-00000917.

³³⁶ [REDACTED] See May 13, 2021 West Gordon Tr. at 110:17-112:14, 123:21-124:5 (repairs); see *id.* at 124:16-125:5 (PMs); see *id.* at 92:16-23 (explaining Restore reached out to Gordon regarding employment in January 2019).

³³⁷ First Amended Complaint ¶ 59, *Restore Robotics LLC v. Intuitive Surgical, Inc.*, Civil Case No. 5:19-cv-00055-MCR-MJF (ECF 14) (N.D. Fla.).

³³⁸ *Id.* ¶¶ 55-56.

- (i) “know the meaning of the error codes appearing on the da Vinci robot system to perform repairs on the system”;
- (ii) “test the robot arms during preventative maintenance”; or
- (iii) “remove the reminder message after performing preventative maintenance or repairing the robot system.”³³⁹

187. These limitations are acknowledged even more explicitly in documents reflecting communications between Restore and potential or actual customers of Restore’s da Vinci system service. For example, as part of its agreement to provide service to Ardent Health Care (“Ardent”), Restore stated that its service program had the following limitations:

- Restore is unable to remotely access internal information such as log files, error messages, etc.
- Restore is unable to access system software or utilize system software in any repair scenario including but not limited to removing error messages or the Preventative Maintenance recommended message.
- If accessing software is required to
 - Test an issue,
 - Diagnose as issue.
 - Resolve an issue.
 - Remove an error message.

³³⁹ *Id.* ¶¶ 56-58. As another example, Restore Field Service Engineer West Gordon testified that when a particular location in Tulsa “had issues . . . with an arm, and it was having an occasional fault, intermittent faults,” he “told them there was no way for me to guarantee that there was nothing more wrong with it,” because there was “no way to run” the proper tests without the MATLAB software on the Intuitive field service laptop. *See* May 13, 2021 West Gordon Tr. at 117:15-119:18.

- Internally register a new part so that the surgical robot may accept it *the customer will need to engage the OEM to support those outcomes.*³⁴⁰

188. Similar acknowledgments can be found in Restore’s “Preventative Maintenance Certificates.” In one example, the Restore Field engineer noted “[t]here was no software access for any PM tests which required Software access to complete appropriate tests. Unable to Complete Software Driven Tests.”³⁴¹

189. However, these acknowledgements do not fully explain how Restore’s preventative maintenance and/or repair processes are rendered ineffective by the limitations identified. Major portions of da Vinci system maintenance and repair require access to Intuitive’s proprietary software to test, diagnose or resolve an issue—something that Restore admittedly cannot accomplish.

190. More specifically, with Restore’s acknowledged technological limitations, it cannot perform the complete preventative maintenance offered by Intuitive. In particular, Restore cannot programmatically test cable tension, MTM calibration, battery voltage, or sine cycles.³⁴² Restore also cannot perform any form of Slow Sweep test, which measures friction and voltages. Restore is further unable to fully review error logs and perform system diagnostics.

191. If these preventative maintenance tests are correctly performed, the results may dictate remedial actions be taken, including the recalibration or replacement of portions of the da

³⁴⁰ AHS_MGMT-INTUITIVE_0000312; AHS_MGMT-INTUITIVE_0000313 at 318 (emphasis added).

³⁴¹ Restore-00025717 (Restore IS3000 Preventative Maintenance, Results Sheet).

³⁴² See *supra* § IX.B.1. Restore appears to perform portions of these preventative maintenance tests manually. See Restore-00025717 (Restore IS3000 Preventative Maintenance, Results Sheet).

Vinci system (e.g., the PSM, the manipulator, battery or PSM brake gear.)³⁴³ As a result, Restore's failure or inability to conduct (or properly conduct) the preventative maintenance tests detailed above could easily leave critical issues unidentified and unaddressed. For example, and as described above, improper preventative maintenance could lead to jerky or non-intuitive da Vinci motion, battery failure, or improper EndoWrist instrument grasping or motion. In addition, if preventative maintenance conducted by Restore fails to identify the need to replace part of the da Vinci system, the da Vinci system may be used in surgery with defective parts. All of these issues can cause harm to a patient during a surgical procedure.

192. Further, although Restore's PM Only program was held out as giving customers "the confidence and certainty of knowing that the surgical robot remains within 'spec,'" Restore's Lead Senior Field Service Engineer, West Gordon, testified differently:

Q. When you performed P.M.s on da Vinci robots for Restore, were you able to guarantee to customers that the robots remained within O.E.M. specifications?

A. Absolutely not. No.

Q. Okay.

A. And I was very clear about that.³⁴⁴

193. Furthermore, even if Restore identified an issue through preventative maintenance, it appears unlikely Restore would have the technological capability to fix the issue. It is unclear if Restore can effectively perform any repairs at all without access to the software needed to verify and calibrate replacement parts to the da Vinci system. Restore's own "spot

³⁴³ See *supra* § IX.B.1. Restore also does not appear to conduct a PSM Brake Test, or at least any PSM Brake Test that follows a similar process to Intuitive's own test. Compare Intuitive-00705431 with Restore-00025717 (Restore IS3000 Preventative Maintenance, Results Sheet).

³⁴⁴ See May 13, 2021 West Gordon Tr. at 143:25-144:6.

repairs” document suggests the customer may need to rely on Intuitive to provide the relevant replacement part,³⁴⁵ and Restore’s agreement with Ardent states that Intuitive would also need to register the new part and perform any needed tests.³⁴⁶ These steps, which Restore acknowledges it cannot perform, are essential in the parts replacement process. Even if Restore could provide a replacement part, without Intuitive’s software, it is possible that the part will not be correctly calibrated or registered with the system. Older replacement parts also may be operating on a different, incompatible firmware than the other parts of the system, which cannot be updated without proprietary software.³⁴⁷

194. These issues with Restore’s PM and spot repair offerings also appear to be reflected in their actual service activities with customers. It is my understanding Restore has only attempted to provide service to a small number of hospitals,³⁴⁸ and I also understand several of those hospitals have had problems with Restore’s service shortly after they agreed to have Restore service their da Vinci systems. For example, with Ardent (which controls Hillcrest Medical Centers (“Hillcrest”)), a da Vinci system arm failed and required immediate replacement. But when Hillcrest reached out to Restore for repair services pursuant to the parties’ agreement,³⁴⁹ Restore told Hillcrest that the repair would have to be done by Intuitive because Restore would need access to the software.³⁵⁰ In addition, after Intuitive FSEs were asked to perform service on the da Vinci systems at Hillcrest that Restore could not complete,

³⁴⁵ Restore-00002095 at Restore-00002096.

³⁴⁶ AHS_MGMT-INTUITIVE_0000312; AHS_MGMT-INTUITIVE_0000313.

³⁴⁷ Interview with Ron Bair, August 19, 2021.

³⁴⁸ See May 13, 2021 West Gordon Tr. at 110:17-112:14.

³⁴⁹ AHS_HMC-INTUITIVE_0000039.

³⁵⁰ *Id.*

they discovered that the PSC battery calibration seal was broken and that the battery needed to be replaced.³⁵¹

195. Similarly, at Baylor, Scott and White Health, Intuitive observed a litany of issues after Restore began attempting to provide service. These issues included: Low cable tension that could impair intuitive motion and impact patient safety; improper connection of the vision system; illuminator errors, broken battery box seals, and multiple hospital employees expressing concerns about the quality of maintenance and the lack of proper software tools for performing proper system maintenance.³⁵² In at least one instance, these issues rendered a da Vinci system unavailable to be used for surgery.³⁵³

196. In conclusion, it is my opinion that Restore's da Vinci service is insufficient to identify or address important issues that can lead to improper functioning of the surgical robot and potentially cause harm to patients. As detailed above, the Restore "PM Only" program does not replicate the Intuitive preventive maintenance procedures and cannot detect problems that can result in inappropriate motion or failure of the robot during surgery. Similarly, the "Spot Repair" program only addresses a few relatively minor service issues and cannot address critical issues that can prevent the da Vinci system from functioning. Restore service offerings do not provide comparable service to that offered by Intuitive and are inadequate to assure that the da Vinci system will reliably function.

³⁵¹ AHS_MGMT000007 at 007-008. As mentioned above, breaking the battery calibration seal is contrary to Intuitive's own servicing procedures for defective batteries and can void calibration on the battery itself. *See* Intuitive-00705155 at Intuitive-00705173-76.

³⁵² Intuitive-00008958 at Intuitive-00008958-59.

³⁵³ *Id.*

I declare under penalty of perjury that the foregoing is true and correct. Executed this 18th day of January, 2023, at Brewster, Massachusetts.

A handwritten signature in black ink, appearing to read "Robert D. Howe", is written over a horizontal line.

Robert D. Howe, Ph.D.
January 18, 2023

Appendix A

Robert D. Howe

Harvard University
Paulson School of Engineering and Applied Sciences
4.218 Science and Engineering Complex
150 Western Ave., Boston, MA 02134 USA

office phone: +1 (617) 496-8359
mobile phone: +1 (617) 877-0930
howe@seas.harvard.edu
<http://biorobotics.harvard.edu>

Employment

- 1997-present **Abbott and James Lawrence Professor of Engineering**, Harvard Paulson School of Engineering and Applied Sciences. Conducting research in robotic manipulation, tactile sensing, surgical robotics, medical image processing, human-machine interfaces, and biomechanics; teaching graduate and undergraduate engineering courses.
- 1994-1997 **Associate Professor of Mechanical Engineering**, Harvard University
- 1990-1994 **Assistant Professor of Mechanical Engineering**, Harvard University
- 1984-1990 **Research Assistant**, Mechanical Engineering Department, Stanford University
- 1981-1983 **Research Physicist**, High Temperature Gasdynamics Laboratory, Stanford University. Developed optical and electronic research instruments, conducted flow visualization and combustion diagnostics experiments.
- 1979-1981 **Electronics Engineer**, Kratos Display Systems, Los Gatos, CA. Designed analog and digital electronics.

Secondary Academic Appointments

- Founding Co-Director, Harvard MS/MBA Program (Dual Master's degree program between Harvard's Business and Engineering Schools), 2018-present
- Area Dean for Bioengineering (equivalent to department chair), Harvard Paulson School of Engineering and Applied Sciences, 2010-2011, 2012-2016
- Associate Dean for Academic Programs (Chief Academic Officer), Harvard School of Engineering and Applied Sciences, 2008-2011
- Adjunct Professor, Department of Biomedical Engineering, Tufts University, 2007 - present
- Member of the Core Faculty, Harvard-MIT Division of Health Sciences and Technology, 1999 - present

Thinker in Residence, Deakin University, Australia, Fall 2015

Visiting Professor, Singapore University of Technology and Design, Spring 2012

Visiting Scientist, INRIA Sophia-Antipolis, France, Spring 2004

Visiting Scholar, Mechanical Engineering Department, Stanford University, Spring 1999

Visiting Scientist, Artificial Intelligence Laboratory, Massachusetts Institute of Technology, Fall 1998

Education

- 1990 Doctor of Philosophy in Mechanical Engineering, Stanford University.
- 1985 Master of Science in Mechanical Engineering, Stanford University.
- 1979 Bachelor of Arts in Physics, Reed College.

Selected Professional Awards and Honors

Fellow, Institute of Electrical and Electronics Engineers (IEEE), 2012.
 Fellow, American Institute for Medical and Biological Engineering (AIMBE), 2007.
 I.S. Ravdin Lecture, American College of Surgeons 97th Annual Clinical Congress, San Francisco, 2011.
 Keynote address, 5th International Conference on Functional Imaging and Modeling of the Heart, Nice, France, 2009.
 Keynote address, SPIE Medical Imaging Conference, San Diego, 2008.
 Keynote address, EuroHaptics Conference, Munich, 2004.
 Whitaker Foundation Biomedical Engineering Research Grant (Career development award), 1995.
 National Science Foundation Young Investigator Award, 1993.

Selected Professional Service

Journals

Associate Editor, *International Journal of Robotics Research*, 2019-present
 Advisory Board, *Science Robotics*, 2017-present.
 Editorial Board, *Medical Image Analysis*, 2008-present.
 Management Committee, Founding member, *IEEE Transactions on Haptics*, 2007-2013.
 Associate editor, *IEEE Transactions on Robotics and Automation*, 1994-1998.

Conferences and workshops

Co-organizer, Workshop on Closing the Loop on Upper-Limb Assistive Device Design, Sensing, Control, & Clinical Practice, IEEE RAS/EMBS International Conference on Biomedical Robotics & Biomechatronics (BioRob), August 21, 2022, Seoul.
 Co-organizer, Tutorial on Jamming in Robotics: From Fundamental Building Blocks to Robotic Applications, IEEE International Conference on Robotics and Automation (ICRA), May 23, 2022, Philadelphia.
 Program Co-Chair, International Conference on Medical Image Computing and Computer-Assisted Intervention (MICCAI), 2014; Program Committee, 1998, 2000, 2002-2007, 2016, 2017.
 Program Committee, Intl. Symposium on Medical Robotics and Computer Assisted Surgery, 1994, 1995, 1997.
 Program Committee, Intl. Conference on Functional Imaging and Modeling of the Heart, 2009, 2011, 2013.
 Area Chair, Robotics: Science and Systems Conference (RSS), Philadelphia, August 16th-19th, 2006 and Cambridge, July 12-16, 2017; program committee member 2007, 2018.
 Co-Chair, International Program Committee, First IEEE World Haptics Conference (First Joint Eurohaptics Conference and Symposium on Haptic Interfaces for Virtual Environment and Teleoperator Systems), Pisa, Italy, 18-20 March, 2005.
 Chair and Organizer, Annual Symposium on Haptic Interfaces for Virtual Environment and Teleoperator Systems, Atlanta, Nov. 1996; Dallas, Nov. 1997; and Anaheim, 1998 (with Susan J. Lederman); program committee member, 1999-2008.
 Program Committee, IEEE Intl. Conference on Robotics and Automation, 1994, 1997, 1998, 2005.
 Program Committee, IEEE/RSJ Intl. Conference on Intelligent Robots and Systems (IROS), 2004.
 Program Committee, Second Intl. Symposium on Medical Simulation, 2004.

Program Committee, Intl. Symposium on Surgery Simulation and Soft Tissue Modeling (IS4TM 2003), Juan-Les-Pins, France, June 2003.

Program Committee, IEEE Intl. Conference on Systems, Man, and Cybernetics, Tokyo, 1999.

Program Committee, Frontiers of Engineering Symposium, National Academy of Engineering, Irvine, CA, Nov. 1998.

Academic Visiting and Advisory Committees

Advisory Board, Robotics Engineering (RBE) Program, Worcester Polytechnic Institute, 2018-present.

Advisory Board. Department of Mechanical Engineering and Applied Mechanics, University of Pennsylvania, 2015-present.

Visiting Committee, Department of Mechanical Engineering, Stanford University, 2015-16.

Advisory Board, Centre for Autonomous Systems, University of Technology, Sydney, Australia, 2016-2020.

Visiting Committee, Department of Mechanical and Process Engineering (Maschinenbau und Verfahrenstechnik), Eidgenössische Technische Hochschule (ETH) Zürich, 2006-2007.

Government Panels

Strategic Advisory Board, Engineering and Physical Sciences Research Council – United Kingdom Network for Robotics and Autonomous Systems (EPSRC UK-RAS), 2015 – 2020.

Funding Review Panel Member, National Science Foundation, 1994, 2000, 2010, 2014, 2017, 2021, 2022.

DARPA Information Science and Technology (ISAT) Study Group, 2008-2011.

Study section, National Institutes of Health, 2003, 2005.

PUBLICATIONS

Journal Articles

104. Moradi Dalvand M, Nahavandi S, Howe RD, "General Forward Kinematics for Tendon-Driven Continuum Robots," *IEEE Access* **10**:60330-40, 2022
103. Teeple CB, Aktaş B, Yuen MC, Kim GR, Howe RD, Wood RJ, "Controlling Palm-Object Interactions Via Friction for Enhanced In-Hand Manipulation," *IEEE Robotics and Automation Letters* **7**(2):2258-65, 2022. Also presented at the IEEE International Conference on Robotics and Automation, Philadelphia, 2022.
102. Degirmenci A, Howe RD, Perrin DP. "Gaussian Process Regression for Ultrasound Scanline Interpolation." *Journal of Medical Imaging* **9**(3):037001, 2022.
101. Nuckols RW, Lee S, Swaminathan K, Orzel D, Howe RD, Walsh CJ, "Individualization of exosuit assistance based on measured muscle dynamics during versatile walking," *Science Robotics* **6**(60):eabj1362, 2021.
100. Aktaş B, Narang YS, Vasios N, Bertoldi K, Howe RD. "A Modeling Framework for Jamming Structures," *Advanced Functional Materials* **31**(16):2007554, 2021.
99. Narang YS, Aktaş B, Ornellas S, Vlassak JJ, Howe RD, "Lightweight Highly Tunable Jamming-Based Composites," *Soft Robotics* **7**(6):724-35, 2020.
98. Moradi Dalvand M, Nahavandi S, Howe RD, "Slack and Excessive Loading Avoidance in n -tendon Continuum Robots," *IEEE Access* **8**:138730-138742, 2020.
97. Loschak PM, Degirmenci A, Tschabrunn CM, Anter E, Howe RD, "Automatically Steering Cardiac Catheters In Vivo with Respiratory Motion Compensation," *International Journal of Robotics Research* **39**(5): 586-97, 2020.
96. Cheng S, Narang YS, Yang C, Suo Z, Howe RD, "Stick-on large-strain sensors for soft robots," *Advanced Materials Interfaces* **6**(20):1900985, 2019.
95. Moradi Dalvand M, Nahavandi S, Howe RD, "An Analytical Tension Model for Continuum Robots with n Generally Positioned Tendons," *Journal of Medical Robotics Research* **4**(03n04):1942003, 2019.
94. Yamada D, Degirmenci A, Howe RD, "Ultrasound imaging characterization of soft tissue dynamics of the seated human body," *Journal of Biomechanical Engineering* **142**(6), 2020.
93. Vasios N, Narang Y, Aktas B, Howe R, Bertoldi K. "Numerical analysis of periodic laminar and fibrous media undergoing a jamming transition," *European Journal of Mechanics-A/Solids* **75**: 322-329, 2019.
92. Degirmenci A, Perrin DP, Howe RD, "High dynamic range ultrasound imaging," *International Journal of Computer Assisted Radiology and Surgery* **13**(5):721-9, 2018. Also presented at the 9th International Conference on Information Processing in Computer-Assisted Interventions, Berlin, June 20-21, 2018. Winner, Best Paper Award.
91. Gaffney LP, Loschak PM, Howe RD, "A Deployable Transseptal Brace for Stabilizing Cardiac Catheters," *Journal of Mechanical Design* **140**(7):075003, 2018.
90. Moradi Dalvand M, Nahavandi S, Fielding M, Mullins J, Najdovski Z, Howe RD, "Modular Instrument for a Haptically-Enabled Robotic Surgical System (HeroSurg)," *IEEE Access* **6**: 31974-82, 2018.
89. Moradi Dalvand M, Nahavandi S, Howe RD, "An Analytical Loading Model for n -Tendon Continuum Robots," *IEEE Transactions on Robotics* **34**(5):1215-25, 2018.
88. Narang YS, Degirmenci A, Vlassak JJ, Howe RD, "Transforming the Dynamic Response of Robotic Structures and Systems Through Laminar Jamming," *IEEE Robotics and Automation Letters*

- 3(2):688-95, 2018. Also presented at the IEEE International Conference on Robotics and Automation, Brisbane, Australia, May 2018.
87. Wan Q, Howe RD. "Modeling the Effects of Contact Sensor Resolution on Grasp Success." *IEEE Robotics and Automation Letters* 3(3): 1933-1940, 2018. Also presented at the IEEE International Conference on Robotics and Automation, Brisbane, Australia, May 2018.
 86. Yashraj S. Narang, Joost J. Vlassak, and Robert D. Howe, "Mechanically Versatile Soft Machines Through Laminar Jamming," *Advanced Functional Materials* 28(17):1707136, 2018.
 85. Villard P, Hammer P, Perrin D, Del Nido P, Howe, R, "Fast Image-Based Mitral Valve Simulation from Individualized Geometry," *International Journal of Medical Robotics and Computer Assisted Surgery* 14(2):e1880, April 2018.
 84. Gafford J, Ranzani T, Russo S, Degirmenci A, Kesner S, Howe R, Wood R, Walsh C., "Toward Medical Devices with Integrated Mechanisms, Sensors, and Actuators via Printed-Circuit MEMS." *Journal of Medical Devices* 11(1):011007, 2017.
 83. Guggenheim JW, Jentoft LP, Tenzer Y, Howe RD, "Robust and Inexpensive 6-Axis Force-Torque Sensors using MEMS Barometers," *IEEE Transactions on Mechatronics* 22(2): 838-44, 2017.
 82. Loschak P, Brattain L, Howe RD, "Algorithms for Automatically Pointing Ultrasound Imaging Catheters," *IEEE Transactions on Robotics* 33(1):81-91, 2017.
 81. Moradi Dalvand M, Nahavandi S, Howe RD, "Fast vision-based catheter 3D reconstruction," *Physics in Medicine and Biology*, 61(14): 5128, 2016.
 80. Loschak PM, Tenzer Y, Degirmenci A, Howe RD, "A 4-DOF Robot for Positioning Ultrasound Imaging Catheters." *ASME Journal of Mechanisms and Robotics* 8(5):0510161-510169, 2016.
 79. Hammond FL, Kramer RK, Wan Q, Howe RD, Wood RJ, "Soft Tactile Sensor Arrays for Force Feedback in Micromanipulation," *IEEE Sensors Journal* 14(5): 1443 - 1452, 2014.
 78. Jentoft LP, Dollar AM, Wagner CR, Howe RD. "Intrinsic Embedded Sensors for Polymeric Mechatronics: Flexure and Force Sensing," *Sensors* 14(3): 3861-3870, 2014.
 77. Hammer PE, Pacak CA, Howe RD, del Nido PJ. "Straightening of curved pattern of collagen fibers under load controls aortic valve shape," *Journal of Biomechanics* 47(2): 341-346, 2014.
 76. Odhner LU, Jentoft LP, Claffee MR, Corson N, Tenzer Y, Ma RR, Buehler M, Kohout R, Howe RD, Dollar AM, "A compliant, underactuated hand for robust manipulation," *International Journal of Robotics Research* 33(5):736-752, 2014.
 75. Kesner S, Howe R, "Robotic catheter cardiac ablation combining ultrasound guidance and force control," *International Journal of Robotics Research* 33 (4): 631-644, 2014.
 74. Chen L, Bavigadda V, Kofidis T, Howe RD, "Fiber optic projection-imaging system for shape measurement in confined space," *Scientific World Journal*, Article ID 206569, 2014.
 73. Tenzer Y, Jentoft LP, Howe RD, "The Feel of MEMS Barometers: Inexpensive and Easily Customized Tactile Array Sensors," *IEEE Robotics and Automation Magazine* 21(3):89-95, 2014.
 72. Bowthorpe M, Tavakoli M, Becher H, Howe, R, "Smith Predictor Based Robot Control in Teleoperated Image-guided Beating-heart Surgery," *IEEE Journal of Biomedical and Health Informatics* 18(1): 157-166, 2014.
 71. Hammond FL, Talbot SG, Wood RJ, Howe RD. "Measurement System for the Characterization of Micro-Manipulation Motion and Force." *Journal of Medical Devices* 7(3): 030940, 2013.
 70. Yuen SG, Nikolay VV, del Nido PJ, Howe RD, "Robotic Tissue Tracking for Beating Heart Mitral Valve Surgery," *Medical Image Analysis* 17(8): 1236-1242, 2013.
 69. Schneider RJ, Perrin DP, Vasilyev NV, Marx GR, Del Nido PJ, Howe RD, "Real-time image-based rigid registration of three-dimensional ultrasound," *Medical Image Analysis* 16(2):402-14, 2012.

68. Hammer PE, Chen PC, del Nido PJ, Howe RD, "Computational model of aortic valve surgical repair using grafted pericardium," *Journal of Biomechanics* **45**(7):1199–1204, 2012.
67. Schneider RJ, Perrin DP, Vasilyev NV, Marx GR, del Nido PJ, Howe RD, "Mitral annulus segmentation from four-dimensional ultrasound using a valve state predictor and constrained optical flow," *Medical Image Analysis* **16**(2):497-504, 2012.
66. Dollar AM, Howe RD, "Joint Coupling Design of Underactuated Hands for Unstructured Environments," *International Journal of Robotics Research*, 30(9):1157-1169, 2011.
65. Kesner SB and Howe RD, "Design Principles for the Rapid Prototyping of Forces Sensors using 3D Printing," *IEEE/ASME Transactions on Mechatronics* **16**(5):866-870, 2011.
64. Kesner SB and Howe RD, "Position Control of Motion Compensation Cardiac Catheters," *IEEE Transactions on Robotics* **27**(6):1045-1055, 2011.
63. Hammer PE, Sacks MS, del Nido PJ, Howe RD, "Mass-Spring Model for Simulation of Heart Valve Tissue Mechanical Behavior," *Annals of Biomedical Engineering* **39**(6):1668-1679, 2011
62. Jordan P, Kerdok AE, Howe RD, and Socrate S, "Identifying a Minimal Rheological Configuration: A Tool for Effective and Efficient Constitutive Modeling of Soft Tissues," *Journal of Biomechanical Engineering* 133(4):041006, April 2011.
61. Yip MC, Tavakoli M, Howe RD, "Performance Analysis of a Haptic Telemanipulation Task under Time Delay," *Advanced Robotics* **25**(5): 651-673, 2011.
60. Nakatani M, Howe RD, Tachi S, "Surface texture can bias tactile form perception," *Experimental Brain Research* **208**(1):151-6, 2011.
59. Yuen SG, Perrin DP, Vasilyev NV, del Nido PJ, Howe RD, "Force Tracking With Feed-Forward Motion Estimation for Beating Heart Surgery," *IEEE Transactions on Robotics* **26**(5): 888-896, 2010.
58. Schneider RJ, Perrin DP, Vasilyev NV, Marx GR, del Nido PJ, Howe RD, "Mitral annulus segmentation from 3D ultrasound using graph cuts," *IEEE Transactions on Medical Imaging* **29**(9):1676-87, 2010.
57. Dollar AM, Howe RD, "The Highly Adaptive SDM Hand: Design and Performance Evaluation," *International Journal of Robotics Research* **29**(5):585–597, 2010.
56. Yip MC, Yuen SG, Howe RD, "A Robust Uniaxial Force Sensor for Minimally Invasive Surgery," *IEEE Transactions on Biomedical Engineering* **57**(5):1008-11, 2010.
55. Rudoy D, Yuen S, Howe RD, Wolfe PJ, "Bayesian changepoint analysis with application to atomic force microscopy and soft material indentation," *Journal of the Royal Statistical Society Series C* **59**(4):573-593, 2010.
54. Dollar AM, Jentoft LP, Gao JH, Howe RD, "Contact sensing and grasping performance of compliant hands" *Autonomous Robotics* **28**(1):65-75, 2010.
53. Perrin DP, Vasilyev NV, Novotny P, Stoll J, Howe RD, Dupont P, Salgo, del Nido PJ, "Image Guided Surgical Interventions," *Current Problems in Surgery* **46**(9): 730-766, 2009.
52. Beasley RA and Howe RD, "Increasing accuracy in image-guided robotic surgery through tip tracking and model-based flexion correction," *IEEE Transactions on Robotics* **25**(2):292-302, 2009.
51. Yuen SG, Kettler DT, Novotny PM, Plowes RD, and Howe RD, "Robotic Motion Compensation for Beating Heart Intracardiac Surgery," *International Journal of Robotics Research* **28**(10): 1355-1372, 2009.
50. Tavakoli M and Howe RD, "Haptic Effects of Surgical Teleoperator Flexibility," *International Journal of Robotics Research* **28**(10):1289-1302, 2009.
49. Balasubramanian R, Howe RD, Matsuoka Y, "Task Performance is Prioritized Over Energy Reduction," *IEEE Transactions on Biomedical Engineering* **56**(5):1310-7, 2009.

48. Jordan P, Socrate S, Zickler TE, Howe RD, "Constitutive modeling of porcine liver in indentation using 3D ultrasound imaging," *Journal of the Mechanical Behavior of Biomedical Materials* **2**(2):192-201, 2009. NIHMSID 99487
47. Vasilyev NV, Novotny PM, Martinez JF, Loyola H, Salgo IS, Howe RD, del Nido PJ. "Stereoscopic Vision Display Technology in Real-Time Three-Dimensional Echocardiography-Guided Intracardiac Beating-Heart Surgery." *Journal of Thoracic and Cardiovascular Surgery* **135**(6):1334-41, 2008.
46. Nakatani M, Howe RD, Tachi S, "Tactile depth perception examined by the Fishbone Tactile Illusion," *Transactions of the Virtual Reality Society of Japan* **13**(1): 97-100, 2008 (in Japanese).
45. Linguraru MG, Vasilyev NV, Marx GM, Tworetzky W, del Nido PJ, Howe RD, "Fast Block Flow Tracking of Atrial Septal Defects in 4D Echocardiography," *Medical Image Analysis* **12**(4):397-412, 2008.
44. Diamond SG, Davis OC, Howe RD, "Heart rate variability as a quantitative measure of trance depth," *International Journal of Clinical and Experimental Hypnosis* **56**(1):1-18, 2008.
43. Novotny PM, Stoll JA, Vasilyev NV, Del Nido PJ, Dupont PE, Howe RD, "GPU Based Real-time Instrument Tracking with Three Dimensional Ultrasound," *Medical Image Analysis* **11**(5):458-64, 2007. NIHMSID 31449
42. Linguraru MG, Kabla A, Marx GR, del Nido PJ, Howe RD, "Real-Time Tracking and Shape Segmentation of Atrial Septal Defects in 3D Echocardiography," *Academic Radiology* **14**:1298-1309, 2007.
41. Wagner CR, Howe RD, "Force Feedback Benefit Depends on Experience in Multi Degree of Freedom Robotic Surgery Task," *IEEE Transactions on Robotics* **23**(6): 1235-1240, 2007.
40. Linguraru MG, Vasilyev NV, del Nido PJ, Howe RD, "Statistical Segmentation of Surgical Instruments in 3D Ultrasound Images," *Ultrasound in Medicine and Biology* **33**(8): 1428-37, 2007.
39. Wagner CR, Stylopoulos N, Jackson PG, Howe RD, "The Benefit of Force Feedback in Surgery: Examination of Blunt Dissection," *Presence* **16**(3): 252-262, June 2007.
38. Novotny PM, Jacobsen SK, Vasilyev NV, Kettler DT, Salgo IS, Dupont PE, del Nido PJ, and Howe RD, "3D ultrasound in robotic surgery: performance evaluation with stereo displays," *International Journal of Medical Robotics and Computer Assisted Surgery*, **2**(3):279-285, 2006.
37. Diamond SG, Davis OC, Schaechter JD, Howe RD, "Hypnosis for Rehabilitation after Stroke: Six Case Studies," *Contemporary Hypnosis* **23**(4), 173-180, 2006.
36. Kerdok AE, Ottensmeyer MP and Howe RD, "The effects of perfusion on the viscoelastic characteristics of liver," *Journal of Biomechanics* **39**(12):2221-31, 2006.
35. Dollar AM and Howe RD, "A Robust Compliant Grasper via Shape Deposition Manufacturing," *IEEE/ASME Transactions on Mechatronics* **11**(2):154-161, April 2006.
34. Suematsu Y, Martinez JF, Wolf BK, Marx GR, Stoll JA, DuPont PE, Howe RD, Triedman JK, del Nido PJ. "Three-dimensional echo-guided beating heart surgery without cardiopulmonary bypass: atrial septal defect closure in a swine model," *Journal of Thoracic and Cardiovascular Surgery* **130**(5):1348-57, November 2005.
33. Gunter HE, Howe RD, Zeitels SM, Kobler JB, Hillman RE, "Measurement of vocal fold collision forces during phonation: Methods and preliminary data" *Journal of Speech, Language, and Hearing Research* **48**(3):567-76, June 2005.
32. Dollar AM, Howe RD, "Towards grasping in unstructured environments: Grasper Compliance and Configuration optimization," *Advanced Robotics*, **19**(5):523-543, June 2005.
31. T.J. Debus P.E. Dupont, and R.D. Howe, "Distinguishability and Identifiability Testing of Contact State Models," *Advanced Robotics*, **19**(5):545-566, June 2005.

30. Samosky J, Burstein D, Grimson WE, Howe R, Martin S, Gray ML. Spatially-localized correlation of dGEMRIC-measured GAG distribution and mechanical stiffness in the human tibial plateau *Journal of Orthopedic Research* **23**(1):93-101, January 2005.
29. Suematsu Y, Marx GR, Stoll JA, DuPont PE, Cleveland RO, Howe RD, Triedman JK, Mihaljevic T, Mora BN, Savord BJ, Salgo IS, del Nido PJ, "Three-dimensional echocardiography-guided beating-heart surgery without cardiopulmonary bypass: a feasibility study," *Journal of Thoracic and Cardiovascular Surgery* **128**(4):579-87, October 2004.
28. T. Debus, T.-J. Jang, P. Dupont, and R. Howe, "Multi-Channel Vibrotactile Display for Teleoperated Assembly," *International Journal of Control, Automation & Systems* **2**(3):390-397, September 2004.
27. C.R. Wagner, S.J. Lederman, R.D. Howe, "Design and Performance of a Tactile Shape Display Using RC Servomotors," *Haptics-e* **3**(4), August 2004.
26. T.J. Debus, P.E. Dupont, and R. D. Howe, "Contact State Estimation using Multiple Model Estimation and Hidden Markov Models," *International Journal of Robotics Research* **23**(4-5):399-413, April-May 2004.
25. J.W. Cannon, J.A. Stoll, S.D. Selha, P.E. Dupont, R.D. Howe, and D.F. Torchiana, "Port Placement Planning in Robot-Assisted Coronary Artery Bypass," *IEEE Transactions on Robotics and Automation* **19**(5): 912-17, October 2003.
24. J. W. Cannon, J. A. Stoll, I. S. Salgo, H. B. Knowles, R. D. Howe, P. E. Dupont, G. R. Marx, and P. J. del Nido, "Real Time 3-Dimensional Ultrasound for Guiding Surgical Tasks," *Computer Aided Surgery* **8**(3):82-90, 2003.
23. Cannon JW, Howe RD, Dupont PE, Triedman JK, Marx GR, del Nido PJ. "Application of robotics in congenital cardiac surgery," *Seminars in Thoracic and Cardiovascular Surgery - Pediatric Cardiac Surgery Annual* **6**:72-83, 2003.
22. A.E. Kerdok, S.M. Cotin, M.P. Ottensmeyer, A.M. Galea, R.D. Howe, and S.L. Dawson, "Truth Cube: Establishing Physical Standards for Real-Time Soft Tissue Simulation," *Medical Image Analysis* **7**(3):283-91, September 2003.
21. Diamond S.G., Howe R.D., "Measuring Hypnosis: Relating the Subjective Experience to Systematic Physiological Changes," *InterJournal of Complex Systems*, 541, 2002.
20. Wellman, P.S, Dalton, E.P., Krag, D., Kern, K.A., Howe, R.D. "Tactile Imaging of Breast Masses: First Clinical Report," *Archives of Surgery* **136**(2):204-08 Feb. 2001.
19. Pawluk, D.T.V. and Howe, R. D. "Dynamic contact of the human fingerpad against a flat surface." *ASME Journal of Biomechanical Engineering* **121**(6):605-611, December 1999.
18. P. Dupont, T. Schulteis, P. Millman, and R. D. Howe, "Automatic Identification of Environment Haptic Properties," *Presence* **8**(4):392-409, August 1999.
17. Pawluk, D.T.V. and Howe, R. D. "Dynamic Lumped Element Response of the Human Fingerpad." *ASME Journal of Biomechanical Engineering* **121**(2):178- 184, April 1999.
16. R. D. Howe and Y. Matsuoka, "Robotics for surgery," *Annual Review of Biomedical Engineering*, **1**:211-240, 1999.
15. D. T. V. Pawluk, J. S. Son, P. S. Wellman, W. J. Peine, and R. D. Howe. "A Distributed Pressure Sensor for Biomechanical Measurements," *ASME Journal of Biomechanical Engineering* **102**(2):302-305, April 1998.
14. A.Z. Hajian and R.D. Howe, "Identification of the mechanical impedance at the human finger tip," *ASME Journal of Biomechanical Engineering*, 119(1):109-114, Feb. 1997. Also presented at the International Mechanical Engineering Congress, American Society of Mechanical Engineers, Chicago, IL, November 1994, Proceedings ed. C. J. Radcliffe, DSC-vol. 55-1, p. 319-327.
13. R. D. Howe and M. R. Cutkosky, "Practical force-motion models for sliding manipulation," *International Journal of Robotics Research* **15**(6):557-572, December 1996.

12. J. S. Son, M. R. Cutkosky, and R. D. Howe, "Comparison of contact sensor localization abilities during manipulation," *Robotics and Autonomous Systems*, **17**(4):217-233, June 1996. Also presented at IROS '95: IEEE/RSJ International Conference on Intelligent Robots and Systems, Pittsburgh, PA, August 5-9, 1995, Proceedings vol. 2, p. 96-101.
11. D. A. Kontarinis and R. D. Howe, "Tactile display of vibratory information in teleoperation and virtual environments," *Presence*, **4**(4):387-402, 1995.
10. R. D. Howe, W. J. Peine, D. A. Kontarinis, and J. S. Son, "Remote palpation technology," *IEEE Engineering in Medicine and Biology*, **14**(3):318-323, May/June 1995.
9. R. D. Howe, "Tactile sensing and control of robotic manipulation," *Journal of Advanced Robotics*, **8**(3):245-261, 1994.
8. R. D. Howe and M. R. Cutkosky, "Dynamic tactile sensing: Perception of fine surface features with stress rate sensing," *IEEE Transactions on Robotics and Automation* **9**(2):140-151, April 1993.
7. B. Edin, R. D. Howe, G. Westling, and M. R. Cutkosky, "A physiological method for relaying frictional information to a human teleoperator," *IEEE Transactions on System, Man, and Cybernetics*, **23**(2):427-432, March/April 1993.
6. M. G. Allen, R. D. Howe, and R. K. Hanson, "Digital imaging of reaction zones in hydrocarbon-air flames using planar laser-induced fluorescence," *Optics Letters* **11**:126-128, 1986.
5. G. Kychakoff, R.D. Howe, R.K. Hanson, M.D. Drake, R. Pitz, M. Lapp, and C.M. Penny, "The visualization of turbulent flame fronts with planar laser-induced fluorescence," *Science* **224**:382-384, 1984.
4. G. Kychakoff, K. Knapp, R. D. Howe, and R. K. Hanson, "Flow visualization in combustion gases using nitric oxide fluorescence," *American Institute of Aeronautics & Astronautics Journal* **22**:153, 1984.
3. G. Kychakoff, R. D. Howe, and R. K. Hanson, "Quantitative flow visualization techniques for measurements in combustion gases," *Applied Optics* **23**:704-712, 1984. Also presented at the Ninth International Colloquium on Explosions and Reactive Systems, Poitier, France, July 1983, and reprinted in R. N. Hindy and J. H. Hunt, eds, *Selected Papers on Laser Beam Diagnostics*, SPIE Milestone Series vol. MS 126, Bellingham, WA, SPIE Optical Engineering Press, 1996.
2. G. Kychakoff, R. D. Howe, and R. K. Hanson, "Spatially resolved combustion measurements using cross-beam saturated absorption spectroscopy," *Applied Optics* **23**:1303-1305, 1984. Also presented at the 1982 Conference on Lasers and Electro-Optics Phoenix, AZ, April 14-16, 1982.
1. G. Kychakoff, R. D. Howe, R. K. Hanson, and J. C. McDaniel, "Quantitative visualization of combustion species in a plane," *Applied Optics* **21**:3225-3227, September 15, 1982.

Refereed Conference Papers

126. Koenig A, Liu Z, Janson L, Howe R, "The Role of Tactile Sensing in Learning and Deploying Grasp Refinement Algorithms," *Proceedings of the IEEE/RSJ Int. Conf. on Intelligent Robots and Systems (IROS)*, October 23–27, 2022, Kyoto, Japan.
125. B. Aktaş and R. D. Howe, "Tunable Anisotropic Stiffness with Square Fiber Jamming," *Proceedings of the 3rd IEEE International Conference on Soft Robotics (RoboSoft)*, New Haven, CT, USA, 2020, pp. 879-884.
124. Ouyang R, Howe R. "Low-Cost Fiducial-based 6-Axis Force-Torque Sensor," *Proceedings of the IEEE International Conference on Robotics and Automation*, May 31, 2020, pp. 1653-1659.

123. Nuckols RW, Swaminathan K, Lee S, Awad L, Walsh CJ, Howe RD, "Automated detection of soleus concentric contraction in variable gait conditions for improved exosuit control," *Proceedings of the IEEE International Conference on Robotics and Automation*, May 31, 2020, pp. 4855-4862.
122. Aktas B, Howe RD, "Flexure Mechanisms with Variable Stiffness and Damping Using Layer Jamming", *Proceedings of the IEEE/RSJ Int. Conf. on Intelligent Robots and Systems (IROS)*, Macau, China, November 3-7 2019.
121. Swaminathan K, Lee S, Nuckols RW, Revi DA, Singh P, Howe RD, Smith MA, Walsh CJ, "Biomechanics Underlying Subject-Dependent Variability in Motor Adaptation to Soft Exosuit Assistance," In Masia L, Micera S, Akay M, Pons J (eds), *Converging Clinical and Engineering Research on Neurorehabilitation III. Proc. International Conference on NeuroRehabilitation*, Pisa, Italy, Oct. 2018, Biosystems & Biorobotics vol 21, Springer, Cham.
120. Yamada D, Degirmenci A, Howe RD, "Ultrasound Imaging for Identifying Dynamics of Soft Tissue," *Proceedings of the IEEE International Symposium on Biomedical Imaging (ISBI'18)*, Washington DC, USA, April 4-7, 2018, pp. 1161-65.
119. Loschak P, Degirmenci A, Howe RD, "Predictive Filtering in Motion Compensation with Steerable Cardiac Catheters," *Proceedings of the IEEE International Conference on Robotics and Automation*, Singapore, May 29 - June 3, 2017, pp. 4830-4836.
118. Mohammadi A, Lavranos J, Howe RD, Choong P, Oetomo D. "Grasp Specific and User Friendly Interface Design towards Lowering the Difficulty in Learning to Operate a Myoelectric Hand Prosthesis," *Proceedings of the IEEE International Conference on Rehabilitation Robotics*, London, July 17-20, 2017, pp. 1621-1626.
117. Moradi Dalvand M, Nahavandi S, Howe RD, "High Speed Vision-based 3D Reconstruction of Continuum Robots," *Proceedings of the IEEE International Conference on Systems, Man, and Cybernetics*, Budapest, Hungary, October 9-12, 2016.
116. Wan Q, Adams R, Howe RD, "Variability and Predictability in Tactile Sensing During Grasping," *Proceedings of the IEEE International Conference on Robotics and Automation*, Stockholm, May 16-21, 2016, pp. 158-164.
115. Degirmenci A, Loschak P, Tschabrunn CM, Anter E, Howe RD. "Compensation for Unconstrained Catheter Shaft Motion in Cardiac Catheters," *Proceedings of the IEEE International Conference on Robotics and Automation*, Stockholm, May 16-21, 2016, pp. 4436-42.
114. Faas D, Howe RD, "Case Study for Introductory Mechanical Design Competitions." *Proceedings of the ASME International Design Engineering Technical Conferences and Computers and Information in Engineering Conference*, Boston, August 2015, Paper No. DETC2015-47286, pp. V003T04A020.
113. Degirmenci A, Hammond III FL, Gafford JB, Walsh CJ, Wood RJ, Howe RD, "Design and Control of a Parallel Linkage Wrist for Robotic Microsurgery," *Proceedings of the IEEE/RSJ Int. Conf. on Intelligent Robots and Systems (IROS)*, Hamburg, Germany, September 28 - October 02, 2015.
112. Loschak PM, Burke SF, Zumbro E, Forelli AR, Howe RD, "A Robotic System for Actively Stiffening Flexible Manipulators," *Proceedings of the IEEE/RSJ Int. Conf. on Intelligent Robots and Systems (IROS)*, Hamburg, Germany, September 28 - October 02, 2015.
111. Jentoft LP, Wan Q, Howe RD, "How to Think about Grasping Systems - Basis Grasps and Variation Budgets," *Proceedings of the International Symposium on Robotics Research (ISRR)*, Sestri Levante, Italy, September 12-15, 2015, Springer Tracts in Advanced Robotics, Vol. 2, pp 359-372.
110. Loschak, PM, Tenzer Y, Degirmenci A, Howe RD, "A 4-DOF Robot for Positioning Ultrasound Imaging Catheters." *Proceedings of the ASME 2015 International Design Engineering Technical Conferences & Computers and Information in Engineering Conference (IDETC/CIE)*, August 2-5, 2015, Boston.

109. Moradi Dalvand M, Shirinzadeh, B Nahavandi S, Howe RD "Tissue characterization in medical robotics." *Proceedings of The 23rd IEEE International Symposium on Robot and Human Interactive Communication (RO-MAN)*, pp. 341-346, 2014.
108. Loschak PM, Brattain LJ, Howe RD, "Algorithms for Automated Pointing of Cardiac Imaging Catheters," in Luo X, Reichl T, Mirota D, Soper T, eds., *Computer-Assisted and Robotic Endoscopy, Proceedings of the First International Workshop*, Boston, September 18, 2014, Springer LNCS vol. 8899, pp. 99-109.
107. Brattain LJ, Loschak PM, Tschabrunn CM, Anter E, Howe RD "Instrument tracking and visualization for ultrasound catheter guided procedures," in Linte CA, Yaniv Z, Fallavollita P, Abolmaesumi P, Holmes DR, eds., *Augmented Environments for Computer-Assisted Interventions, Proceedings of the 9th International Workshop*, Boston, September 14, 2014, Springer LNCS vol. 8678, pp. 41-50.
106. Suárez-Ruiz F, Galiana I, Tenzer Y, Jentoft LP, Howe RD, Ferre M. "Grasp Mapping Between a 3-Finger Haptic Device and a Robotic Hand," in Auvray M and Duriez C, eds., *Haptics: Neuroscience, Devices, Modeling, and Applications, Proceedings of the 9th International Conference, EuroHaptics 2014*, Versailles, France, June 24-26, 2014, Springer LNCS vol. 8618, pp. 275-283.
105. Gafford J, Kesner SB, Degirmenci A, Wood R, Howe RD, Walsh CJ, "A Monolithic Approach to Fabricating Low-Cost, Millimeter-Scale Multi-Axis Force Sensors for Minimally-Invasive Surgery," *Proceedings of the IEEE International Conference on Robotics and Automation*, Hong Kong, May 31-June 7, 2014, pp. 1419-25.
104. Jentoft LP, Wan Q, Howe RD, "Limits to Compliance and the Role of Tactile Sensing in Grasping," *Proceedings of the IEEE International Conference on Robotics and Automation*, Hong Kong, May 31-June 7, 2014, pp. 6394-99.
103. Hammond FL, Howe RD, Wood RJ, "Dexterous high-precision robotic wrist for micromanipulation," *Proceedings of the 16th International Conference on Advanced Robotics*, Montevideo, Uruguay, November 25-29th, 2013, IEEE.
102. Jentoft, LP, Tenzer, Y, Vogt, D, Liu, J, Wood, R, and Howe RD, "Flexible, Stretchable Tactile Arrays From MEMS Barometers," *Proceedings of the 16th International Conference on Advanced Robotics*, Montevideo, Uruguay, November 25-29th, 2013 IEEE.
101. Hammer PE, Pacak CA, Howe RD, del Nido PJ, "Collagen bundle orientation explains aortic valve leaflet coaptation," *Proceedings of the Seventh International Conference on Functional Imaging and Modeling of the Heart*, London, June 20-22, 2013, Springer Lecture Notes in Computer Science, Volume 7945, pp 409-415.
100. Tenenholtz NA, Hammer PE, Fabozzo A, Feins EN, del Nido PJ, Howe RD, "Fast Simulation of Mitral Annuloplasty for Surgical Planning," *Proceedings of the Seventh International Conference on Functional Imaging and Modeling of the Heart*, London, June 20-22, 2013, Springer Lecture Notes in Computer Science, Volume 7945, pp. 106-113.
99. Bowthorpe M, Tavakoli M, Becher H, Howe RD, "Smith Predictor Based Control in Teleoperated Image-guided Beating-heart Surgery," , *Proceedings of the IEEE International Conference on Robotics and Automation*, Karlsruhe, Germany, May 6-10, 2013.
98. Loschak PM, Brattain LJ, Howe RD, "Automated Pointing of Cardiac Imaging Catheters," *Proceedings of the IEEE International Conference on Robotics and Automation*, Karlsruhe, Germany, May 6-10, 2013, pp. 5794-99.
98. Kesner SB, Howe RD, "Motion Compensated Catheter Ablation of the Beating Heart Using Image Guidance and Force Control," in Desai JP, Dudek G, Khatib O, Kumar V, eds., *Proceedings of the International Symposium of Experimental Robotics (ISER)*, June 17 - 21, 2012, Québec City, Canada, Springer Tracts in Advanced Robotics vol. 88.

97. Hammond III FL, Kramer RK, Wan Q, Howe RD, Wood RJ, "Soft Tactile Sensor Arrays for Micromanipulation," *Proceedings of the IEEE/RSJ Int. Conf. on Intelligent Robots and Systems (IROS)*, Vilamoura, Portugal, Oct. 7-12, 2012, pp. 25-32
96. Galiana I, Hammond III FL, Howe RD, Popovic MB, "Wearable Soft Robotic Device for Post-Stroke Shoulder Rehabilitation: Identifying Misalignments," *Proceedings of the IEEE/RSJ Int. Conf. on Intelligent Robots and Systems (IROS)*, Vilamoura, Portugal, Oct. 7-12, 2012, pp. 317-322.
95. Brattain LJ, Vasilyev NV, Howe RD, "Enabling 3D Ultrasound Procedure Guidance through Enhanced Visualization," in P. Abolmaesumi, L. Joskowicz, N. Navab and P. Jannin (Eds.), *Proceedings of the International Conference on Information Processing in Computer-Assisted Interventions (IPCAI)*, Pisa, Italy, June 27, 2012, Springer Lecture Notes in Computer Science vol. 7330, pp. 115-124.
94. Hammond III FL, Weisz J, de la Llera Kurth AA, Allen PK, Howe RD, "Towards a Design Optimization Method for Reducing the Mechanical Complexity of Underactuated Robotic Hands," *Proceedings of the IEEE International Conference on Robotics and Automation*, Minneapolis, Minnesota, 2012, pp. 2843-2850.
93. Jentoft L, Howe RD, "Determining Object Geometry with Compliance and Simple Sensors," *Proceedings of the IEEE/RSJ International Conference on Intelligent Robots and Systems (IROS)*, San Francisco, September 25-30, 2011 pp. 1327-1332.
92. Tenenholz NA, Hammer PE, Schneider RJ, Vasilyev NV, and Howe RD, "On the Design of an Interactive, Patient-Specific Surgical Simulator for Mitral Valve Repair," *Proceedings of the IEEE/RSJ International Conference on Intelligent Robots and Systems (IROS)*, San Francisco, September 25-30, 2011 pp. 3468-3473.
91. Schneider RJ, Tenenholz N, Perrin DP, Marx GR, del Nido PJ, Howe RD, "Patient-Specific Mitral Leaflet Segmentation from 4D Ultrasound," *Proceedings of Medical Image Computing and Computer-Assisted Intervention – MICCAI*, Toronto, September 18-22, 2011, Springer Lecture Notes in Computer Science vol. 6893, pp. 520-527.
90. Brattain L and Howe RD, "Real-time 4D Ultrasound Mosaicing and Visualization," *Proceedings of Medical Image Computing and Computer-Assisted Intervention – MICCAI*, Toronto, September 18-22, 2011, Springer Lecture Notes in Computer Science vol. 6891, pp. 105-12.
89. Kesner SB and Howe RD, "Discriminating Tissue Stiffness with a Haptic Catheter: Feeling the Inside of the Beating Heart," *Proceedings of the IEEE World Haptics Conference*, Istanbul, June 22-24, 2011, pp. 13-18.
88. Kesner SB and Howe RD, "Design of a motion compensated tissue resection catheter for beating heart cardiac surgery," *Proceedings of the Design of Medical Devices Conference*, Minneapolis, April 12-14; reprinted in *Journal of Medical Devices* 5(2):027523, 2011.
87. Kesner SB and Howe RD, "Force Control of Flexible Catheter Robots for Beating Heart Surgery" *Proceedings of the IEEE International Conference on Robotics and Automation*, Shanghai, May 9-13, 2011, pp. 1589-1594.
86. Schneider RJ, Perrin DP, del Nido PJ, Howe RD, "Modeling Mitral Valve Leaflets from Three-Dimensional Ultrasound," *Proceedings of the Sixth International Conference on Functional Imaging and Modeling of the Heart*, New York, May 25-27, 2011, Springer Lecture Notes in Computer Science, pp. 215-222.
85. Hammer PE, del Nido PJ, Howe RD, "Anisotropic Mass-Spring Method Accurately Simulates Mitral Valve Closure from Image-Based Models," *Proceedings of the Sixth International Conference on Functional Imaging and Modeling of the Heart*, New York, May 25-27, 2011, Springer Lecture Notes in Computer Science, 233-240.

84. Yip MC, Tavakoli M, Howe RD, "Performance Analysis of a Manipulation Task in Time-Delayed Teleoperation," *Proceedings of the IEEE/RSJ International Conference on Intelligent Robots and Systems (IROS)*, Taipei, October 18-22, 2010, pp. 5270-5275.
83. Yuen SG, Dubec KA, Howe RD, "Haptic Noise Cancellation: Restoring Force Perception in Robotically-Assisted Beating Heart Surgery," *Proceeding of the Haptics Symposium*, IEEE press, Waltham, MA, March 25-26, 2010, pp. 387-392.
82. Kesner SB, Yuen SG, Howe RD, "Design and Control of Motion Compensation Cardiac Catheters," *Proceedings of the IEEE International Conference on Robotics and Automation*, Anchorage, AK, USA, May 4-6, 2010, pp. 1059-1065. (Finalist, Best Medical Robotics Paper Award)
81. Kesner SB, Yuen SG, Howe RD, "Ultrasound Servoing of Catheters for Beating Heart Valve Repair," *Proceedings of the 1st International Conference on Information Processing in Computer-Assisted Interventions (IPCAI)*, Geneva, Switzerland, June 23-24 2010, Navab N. and Jannin, P, eds., Springer Lecture Notes in Computer Science, vol. 6135, pp. 168-178.
80. Yuen SG, Yip MC, Vasilyev NV, Perrin DP, del Nido PJ, and Howe RD, "Robotic Force Stabilization for Beating Heart Intracardiac Surgery," *Proceedings of Medical Image Computing and Computer-Assisted Intervention – MICCAI*, Springer Lecture Notes in Computer Science, vol. 5761, London, September 20-24, 2009, pp. 26-33.
79. Schneider RJ, Perrin DP, Vasilyev NV, Marx GR, del Nido PJ, Howe RD, "Mitral Annulus Segmentation from Three-Dimensional Ultrasound," *Proceedings of the IEEE International Symposium on Biomedical Imaging*, Boston, June 28-July 1, 2009, pp. 779-785.
78. Tadakuma, R and Howe, RD, "A Whole-Arm Tactile Display System," *Proceedings of the Third World Haptics Conference (Joint Eurohaptics Conference and Symposium On Haptic Interfaces for Virtual Environment and Teleoperator Systems)*, IEEE press, Salt Lake City, March 18-20, 2009, pp. 446-451.
77. Yuen SG, Kettler DT, Howe RD, "Robotic motion compensation for beating intracardiac surgery," *Proceedings of the 10th International Conference on Control, Automation, Robotics and Vision (ICARCV)*, Hanoi, December 17-20, 2008, pp. 617-622.
76. Yuen SG, Novotny PM, Howe RD, "Quasiperiodic Predictive Filtering for Robot-Assisted Beating Heart Surgery," to appear in *Proceedings of the IEEE International Conference on Robotics and Automation*, Pasadena, CA, USA, May 9-13, 2008, pp. 3875-3880.
75. Yuen SG, Kesner SB, Vasilyev NV, del Nido PJ, and Howe RD, "3D Ultrasound-Guided Motion Compensation System for Beating Heart Mitral Valve Repair," *Proceedings of Medical Image Computing and Computer-Assisted Intervention – MICCAI*, Springer Lecture Notes in Computer Science, vol. 5241, New York, September 2008, pp. 711-719.
74. Jordan P, Zickler TE, Socrate S, Howe RD, "A Nonrigid Image Registration Framework for Identification of Tissue Mechanical Parameters." *Proceedings of Medical Image Computing and Computer-Assisted Intervention – MICCAI*, Springer Lecture Notes in Computer Science, vol. 5242, New York, September 2008, pp. 930-8.
73. Kettler DT, R.D. Plowes, Novotny PM, Vasilyev NV, del Nido PJ, and Howe RD, "An Active Motion Compensation Instrument for Beating Heart Mitral Valve Surgery," *Proceedings of the IEEE/RSJ International Conference on Intelligent Robots and Systems (IROS)*, San Diego, CA, Oct. 29-Nov. 2, 2007, pp. 1290-1295. (Finalist, Best Student Paper Award)
72. Tavakoli M, Howe RD, "The Effect of Joint Elasticity on Bilateral Teleoperation," *Proceedings of the IEEE/RSJ International Conference on Intelligent Robots and Systems (IROS)*, San Diego, CA, Oct. 29-Nov. 2, 2007, pp. 1618-1623. (Finalist, Best Paper Award)
71. Tadakuma R, Tadakuma K, and Howe RD, "Few D.O.F. Walking Robot with Outer-Wheels," *Proceedings of the IEEE Conference on Automation Science and Engineering (CASE)*, Scottsdale, AZ, USA, September 22-25, 2007, pp. 1117-1124.

70. Dollar AM and Howe RD, "The SDM Hand as a Prosthetic Terminal Device: A Feasibility Study," *Proceedings of the IEEE International Conference on Rehabilitation Robotics (ICORR)*, Noordwijk, the Netherlands, June 13-15, 2007, pp. 978-983. (Best Student Paper Award)
69. Yuen SG, Rudoy D, Howe RD, Wolfe PJ, "Bayesian Change-point Detection Through Switching Regressions: Contact Point Determination in Material Indentation Experiments," IEEE 14th Workshop on Statistical Signal Processing (SSP '07), Madison, Wisconsin, August 26-29, 2007, pp. 104-108.
68. Oyarzábal M, Nakatani M, Howe RD, "Vibration Enhances Geometry Perception with Tactile Shape Displays," *Proceedings of the Second World Haptics Conference (Joint Eurohaptics Conference and Symposium on Haptic Interfaces for Virtual Environment and Teleoperator Systems)*, Tsukuba, Japan, March 22-24, 2007, IEEE Computer Society Press, pp. 44-49.
67. Linguraru MG, Kabla A, Vasilyev NV, del Nido PJ, Howe RD, "Real-time block flow tracking of atrial septal defect Motion in 4D cardiac ultrasound," *Proceedings of the Fourth IEEE International Symposium on Biomedical Imaging*, Washington, DC, April 12-15, 2007, pp. 356-359.
66. P. Novotny, J. Stoll, P. Dupont, R.D. Howe, "Real-Time Visual Servoing of a Robot Using Three Dimensional Ultrasound," *Proceedings of the IEEE International Conference on Robotics and Automation*, Rome, April 2007, pp. 2655 - 2660.
65. A.M. Dollar, R.D. Howe, "Simple, Robust Autonomous Grasping in Unstructured Environments," *Proceedings of the IEEE International Conference on Robotics and Automation*, Rome, April 2007, pp. 4693 - 4700.
64. Novotny, PM, Stoll, JA, Vasilyev, NV, Del Nido, PJ, Dupont, PE, Howe, RD, "GPU Based Real-time Instrument Tracking with Three Dimensional Ultrasound," in R. Larsen, M. Nielsen and J. Sporring, eds., *Proceedings of Medical Image Computing and Computer-Assisted Intervention – MICCAI*, Springer Lecture Notes in Computer Science, vol. 4190, pp. 58-65, Copenhagen, October 2006. (Best Student Paper Award)
63. MG Linguraru, NV Vasilyev, PJ del Nido, RD Howe, "Atrial Septal Defect Tracking in 3D Cardiac Ultrasound, in R. Larsen, M. Nielsen and J. Sporring, eds., *Proceedings of Medical Image Computing and Computer-Assisted Intervention – MICCAI*, Springer Lecture Notes in Computer Science, vol. 4190, pp. 596-603, Copenhagen, October 2006.
62. R. L. Feller, D.P. Perrin, and R.D. Howe, "Validation and Explanation of Waterhammer-Based Locomotion," *Proceedings of the IEEE International Conference on Robotics and Automation*, Orlando, FL, pp. 4264-4269, 2006.
61. J. Stoll, P. Novotny, R.D. Howe, and P. Dupont, "Real-time 3D Ultrasound-based Servoing of a Surgical Instrument," *Proceedings of the IEEE International Conference on Robotics and Automation*, pp. 613-618, Orlando, FL, 2006.
60. A.M. Dollar and R.D. Howe, "Joint Coupling Design of Underactuated Grippers," 30th Annual ASME Mechanisms and Robotics Conference, 2006 International Design Engineering Technical Conferences (IDETC), Philadelphia, PA, Sept. 10-13, 2006. (Best Student Design Award)
59. Wagner CR, Vasilyev N, Perrin DP, del Nido PJ, Howe RD, "Force Feedback in a Three-Dimensional Ultrasound-Guided Surgical Task," *Proceedings of the 14th International Symposium on Haptic Interfaces for Virtual Environment and Teleoperator Systems*, Washington, DC, 2006, IEEE Computer Society Press, pp. 43- 48.
58. Dollar AM, Wagner CR. Howe RD, "Sensors for Biomimetic Robots via Shape Deposition Manufacturing," *Proceedings of the First IEEE/RAS-EMBS International Conference on Biomedical Robotics and Biomechatronics (BioRob2006)*, Pisa, Italy, 2006, IEEE Press, pp. 763- 768.
57. R.A. Beasley, and R.D. Howe, "Model-Based Error Correction for Flexible Robotic Surgical Instruments," *Robotics: Science and Systems I*, Cambridge, Massachusetts, June 2005, <http://www.roboticsproceedings.org/rss01/index.html>.

56. C.R. Wagner, D.P. Perrin, R.L. Feller, R.D. Howe, O. Clatz, H. Delingette, N. Ayache, "Integrating Tactile and Force Feedback with Finite Element Models," *Proceedings of the IEEE International Conference on Robotics & Automation*, Barcelona, April 18-22, 2005, pp. 3942–3947.
55. A.M. Dollar, A. E. Kerdok, S.G. Diamond, P.M. Novotny, and R.D. Howe, "Starting on the Right Track: Introducing Students to Mechanical Engineering with a Project-Based Machine Design Course," *Proceedings of the 2005 ASME International Mechanical Engineering Congress and Exposition (IMECE)*, Mechanical Engineering Education Symposium, IMECE2005-81929, 2005.
54. A.M. Dollar and R.D. Howe, "Design and Evaluation of a Robust Compliant Grasper using Shape Deposition Manufacturing," *Proceedings of the 2005 ASME International Mechanical Engineering Congress and Exposition (IMECE)*, Robotics panel of the Dynamic Systems and Control Division, IMECE2005-79791, 2005.
53. C.R. Wagner, R.D. Howe "Mechanisms of Performance Enhancement With Force Feedback," *Proceedings of the IEEE World Haptics Conference (First Joint Eurohaptics Conference and Symposium on Haptic Interfaces for Virtual Environment and Teleoperator Systems)*, Pisa, Italy, March 18-20, 2005, pp. 21 – 29.
52. M.P. Ottensmeyer, A.E. Kerdok, R.D. Howe, S.L. Dawson, "The Effects of Testing Environment on the Viscoelastic Properties of Soft Tissues," in S. Cotin and D.N. Metaxas, eds., *Proceedings of Medical Simulation: International Symposium - ISMS 2004*, Cambridge, MA, June 17-18, 2004, Springer Lecture Notes in Computer Science vol. 3078, pp. 9-18.
51. A.M. Galea and R.D. Howe, "Liver Vessel Parameter Estimation from Tactile Imaging Information," in S. Cotin and D.N. Metaxas, eds., *Proceedings of Medical Simulation: International Symposium - ISMS 2004*, Cambridge, MA, June 17-18, 2004, Springer Lecture Notes in Computer Science vol. 3078, pp. 59-66.
50. Y. Liu, A.E. Kerdok, R.D. Howe, "A Nonlinear Finite Element Model of Soft Tissue Indentation," in S. Cotin and D.N. Metaxas, eds., *Proceedings of Medical Simulation: International Symposium - ISMS 2004*, Cambridge, MA, June 17-18, 2004, Springer Lecture Notes in Computer Science vol. 3078, pp. 67-76.
49. D.P. Perrin, A. Kwon, and R.D. Howe, "A Novel Actuated Tether Design for Rescue Robots Using Hydraulic Transients," *Proceedings of the IEEE International Conference on Robotics & Automation*, New Orleans, April 26-May 1, 2004, pp. 3482-87.
48. R.A. Beasley, R.D. Howe, and P.D. Dupont, "Kinematic error correction for minimally invasive surgical robots," *Proceedings of the IEEE International Conference on Robotics & Automation*, New Orleans, April 26-May 1, 2004, pp. 358-364.
47. R.L. Feller, C.K.L. Lau, C.R. Wagner, D.P. Perrin, R.D. Howe, "The Effect of Force Feedback on Remote Palpation," *Proceedings of the IEEE International Conference on Robotics & Automation*, New Orleans, April 26-May 1, 2004, pp. 782-88.
46. C.K.L. Lau, C.R. Wagner, and R.D. Howe, "Compliant Background Subtraction Algorithms for Tactile Rendering," *Proceedings of the 12th Symposium on Haptic Interfaces for Virtual Environment and Teleoperator Systems*, Chicago, March 27-28, 2004, IEEE Computer Society Press, pp. 32-39.
45. S.J. Lederman, R.D. Howe, R.L. Klatzky, C. Hamilton, "Force variability during surface contact with bare finger or rigid probe," *Proceedings of the 12th Symposium on Haptic Interfaces for Virtual Environment and Teleoperator Systems*, Chicago, March 27-28, 2004, IEEE Computer Society Press, pp. 154- 160.
44. Dollar and R.D. Howe, "Towards Grasping in Unstructured Environments: Optimization of Grasper Compliance and Configuration," *Proceedings of the 2003 IEEE/RSJ International Conference on Intelligent Robots and Systems (IROS 2003)*, Las Vegas, October 27-31, 2003, pp. 3410-3416.

43. A.M. Galea and R.D. Howe, Mammography Registered Tactile Imaging, in N. Ayache and H. Delingette, eds., *Proceedings of the International Symposium on Surgery Simulation and Soft Tissue Modeling - IS4TM 2003*, Juan-Les-Pins, France, June 12-13, 2003, Springer Lecture Notes in Computer Science vol. 2673, pp. 183-193.
42. J.M. Lee, C.R. Wagner, S.J. Lederman, and R.D. Howe, "Spatial Low Pass Filters for Pin Actuated Tactile Displays," *Proceedings of the 11th Symposium on Haptic Interfaces for Virtual Environment and Teleoperator Systems*, Los Angeles, March 22-23, 2003, IEEE Computer Society Press, pp. 57-62. Dollar AM and Howe RD,
41. R. A. Beasley and R.D. Howe, "Tactile Tracking of Arteries in Robotic Surgery," *Proceedings of the IEEE International Conference on Robotics & Automation*, Washington, DC, May 11 - 15, 2002, pp. 3801-6.
40. T. Debus, T.-J. Jang, P. Dupont and R. Howe, "Multi-channel vibrotactile display for teleoperated assembly," *Proceedings of the IEEE International Conference on Robotics & Automation*, May 11 - 15, 2002, pp. 592-7.
39. C. R. Wagner, N. Stylopoulos, and R. D. Howe, "The Role of Force Feedback In Surgery: Analysis of Blunt Dissection," in *Proceedings of the 10th Symposium on Haptic Interfaces for Virtual Environment and Teleoperator Systems*, Orlando, March 24-25, 2002, IEEE Computer Society Press, pp. 73-79.
38. Wagner, C.R., Lederman, S.J., Howe, R.D., "A Tactile Shape Display Using RC Servomotors," *Proceedings of the 11th Symposium on Haptic Interfaces for Virtual Environment and Teleoperator Systems*, Orlando, March 24-25, 2002, IEEE Computer Society Press, pp. 354 - 355
37. S. S. Park, R. D. Howe, and D. F. Torchiana, "Virtual Fixtures for Robot-Assisted Minimally-Invasive Cardiac Surgery," in W. J. Niessen and M. A. Viergever, eds., *Proc. Fourth International Conference on Medical Image Computing and Computer-Assisted Intervention – MICCAI 2001*, Utrecht, The Netherlands, 14-17 October 2001, Lecture Notes in Computer Science Vol.1679, Springer, Berlin, p. 1419-20.
36. S. Selha ,P. Dupont, R.D. Howe, and D. Torchiana, "Optimal Port Placement in Robot-Assisted Coronary Artery Bypass Grafting," in W. J. Niessen and M. A. Viergever, eds., *Proc. Fourth International Conference on Medical Image Computing and Computer-Assisted Intervention – MICCAI 2001*, Utrecht, The Netherlands, 14-17 October 2001, Springer Lecture Notes in Computer Science Vol.1679.
35. J. P. Desai and R. D.Howe, "Towards the development of a humanoid arm by minimizing interaction forces through minimum impedance control," *Proceedings of the IEEE International Conference on Robotics & Automation*, Seoul, Korea, May 23-25, 2001, pp. 4214-4219.
34. T. Debus, P. Dupont and R.D. Howe, "Automatic identification of local geometric properties during teleoperation," *Proceedings of the IEEE International Conference on Robotics & Automation*, San Francisco, April 2000, pp. 3428-3434.
33. F. Lai and R.D. Howe, "Evaluating Control Modes for Constrained Robotic Surgery," *Proceedings of the IEEE International Conference on Robotics & Automation*, San Francisco, April 2000, pp. 603-609.
32. F. Lai, R.D. Howe, P.A. Millman, and S. Sur, "Frame Mapping And Dexterity For Task Performance In Robotic Endoscopic Surgery," in N. Olgac, ed., *Proc. of the ASME Dynamic Systems and Control Division, ASME International Mechanical Engineering Congress and Exposition*, Nashville, Nov. 14-19, 1999, DSC-Vol. 67.
31. M. Shibata and R.D. Howe, "Effect of Gloving on Perceptual and Manipulation Task Performance," in N. Olgac, ed., *Proc. of the ASME Dynamic Systems and Control Division, ASME International Mechanical Engineering Congress and Exposition*, Nashville, Nov. 14-19, 1999, DSC-Vol. 67.

30. T. Debus P. Dupont, and R.D. Howe, "Automatic Property Identification via Parameterized Constraints," *Proceedings of the IEEE International Conference on Robotics & Automation*, Detroit, May 1999, pp. 1876-81.
29. W.J. Peine and R.D. Howe, "Do humans sense finger deformation or distributed pressure to detect lumps in soft tissue?," in R.J. Furness, ed., *Proceedings of the ASME Dynamic Systems and Control Division*, ASME International Mechanical Engineering Congress and Exposition, Anaheim, Nov. 19-20, 1998, DSC-Vol. 64, pp. 273-278.
28. A. M. Okamura, J. T. Dennerlein and R. D. Howe, "Vibration Feedback Models for Virtual Environments," *Proceedings of the IEEE International Conference on Robotics & Automation*, Leuven, Belgium, May 16-20, 1998, pp. 674-679.
27. W.J. Peine, P.S. Wellman and R. D. Howe, "Temporal bandwidth requirements for tactile shape displays," in G. Rizzoni, ed., *Proceedings of the ASME Dynamic Systems and Control Division*, ASME International Mechanical Engineering Congress and Exposition, Dallas, Nov. 15-21, 1997, DSC-Vol. 61, pp. 107-113.
26. J.T. Dennerlein, P. Millman, and R.D. Howe, "Vibrotactile Feedback for Industrial Telemanipulators," Sixth Annual Symposium on Haptic Interfaces for Virtual Environment and Teleoperator Systems, ASME International Mechanical Engineering Congress and Exposition, Dallas, Nov. 15-21, 1997, DSC-Vol. 61, pp. 189-195.
25. A. Z. Hajian, D. S. Sanchez, and R. D. Howe, "Drum roll: Increasing bandwidth through passive impedance modulation," *Proceedings of the IEEE International Conference on Robotics and Automation*, Albuquerque, New Mexico, April 20 - 25, 1997, pp. 2294-9. (Finalist, best student paper award.)
24. P. E. Dupont, T. M. Schulteis, and R. D. Howe, "Experimental Identification of Kinematic Constraints," *Proceedings of the IEEE International Conference on Robotics and Automation*, Albuquerque, New Mexico, April 20 - 25, 1997, pp. 2677-82.
23. T. Shulteis, P. Dupont, P. Millman, and R. Howe, "Automatic identification of remote environments," Symposium on Haptic Interfaces for Virtual Environment and Teleoperator Systems, ASME International Mechanical Engineering Congress and Exposition, Atlanta, GA, Nov. 17-22, 1996, K. Danai, ed., *Proceedings of the Dynamic Systems and Control Division of the ASME*, DSC-Vol. 58, p. 451-458.
22. J.S. Son, R.D. Howe, J. Wang, and G. D. Hager, "Preliminary results on grasping with vision and touch," *Proceedings of IROS '96: IEEE/RSJ International Conference on Intelligent Robots and Systems*, Osaka, Japan, Nov. 4-8, 1996.
21. D. Hristu, D. A. Kontarinis, and R.D. Howe, "A comparison of delay and bandwidth limitations in teleoperation," *Proceedings of the International Federation of Automatic Controls World Congress*, San Francisco, June 30-July 5, 1996, Elsevier, vol. L, p. 331-336.
20. J. S. Son and R. D. Howe, "Tactile sensing and stiffness control with multifingered hands," *Proceedings of the IEEE International Conference on Robotics and Automation*, Minneapolis, April 22-28, 1996, p. 3228-3233.
19. E. R. Dunn and R. D. Howe, "Foot placement and velocity control in smooth bipedal walking," *Proceedings of the IEEE International Conference on Robotics and Automation*, Minneapolis, April 22-28, 1996, p. 578-583.
18. R. D. Howe, D. A. Kontarinis, and W.J. Peine, "Shape memory alloy actuator controller design for tactile displays," *Proceedings of the 34th IEEE Conference on Decision and Control*, New Orleans, December 13-15, 1995, p. 3540-3544.
17. P. Wellman and R. D. Howe, "Towards realistic vibrotactile display in virtual environments," Symposium on Haptic Interfaces for Virtual Environment and Teleoperator Systems, ASME International Mechanical Engineering Congress and Exposition, San Francisco, November 12-17,

- 1995, T.E. Alberts, ed., Proceeding of the ASME Dynamics Systems and Control Division of the ASME, DSC-Vol. 57-2, p. 713-718.
16. D. A. Kontarinis, J.S. Son, W.J. Peine, and R. D. Howe, "A tactile sensing and display system for teleoperated manipulation," *Proceedings of the 1995 IEEE International Conference on Robotics and Automation*, Nagoya, Japan, May 1995, p. 641-646.
15. W. J. Peine, J. S. Son, and R. D. Howe, "A palpation device for artery localization in laparoscopic surgery," *Proceedings of the First International Symposium on Medical Robotics and Computer Assisted Surgery*, Pittsburgh, PA, Sept. 1994. p. 250-253.
14. E. R. Dunn and R. D. Howe, "Towards smooth biped walking," *Proceedings of the 1994 IEEE International Conference on Robotics and Automation*, San Diego, CA, May 1994, pp. 2489-2494.
13. J. Son, E. A. Monteverde, and R. D. Howe, "A tactile sensor for localizing transient events in manipulation," *Proceedings of the 1994 IEEE International Conference on Robotics and Automation*, San Diego, CA, May 1994, pp. 471-476.
12. R. D. Howe, "A dextrous teleoperated hand system with finger-level force feedback," International Federation of Machines and Mechanisms International Symposium, Nagoya, Japan, September 1992.
11. R. D. Howe, "Tactile sensor selection for dextrous manipulation," IMACS/SICE International Symposium on Robotics, Mechatronics, and Manufacturing Systems, Kobe, Japan, September 1992.
10. R. D. Howe, "A force-reflecting teleoperated hand system for the study of tactile sensing in precision manipulation," *Proceedings of the 1992 IEEE International Conference on Robotics and Automation*, Nice, France, May 1992, pp. 1321-1326.
9. R. D. Howe, "A tactile stress rate sensor for perception of fine surface features," *Proceedings of Transducers '91: Sixth International Conference on Solid-State Sensors and Actuators*, San Francisco, CA, June 23-27, 1991.
8. R. D. Howe and M. R. Cutkosky, "Integrating tactile sensing with control for dextrous manipulation," 1990 IEEE International Workshop on Intelligent Motion Control, Istanbul, Turkey, August 20-22, 1990, pp. 369 – 374.
7. R. D. Howe, N. Popp, I. Kao, P. Akella, and M. Cutkosky, "Grasping, manipulation, and control with tactile sensing," *Proceedings of the 1990 IEEE international Conference on Robotics and Automation*, Cincinnati, OH, May 13-18, 1990.
6. R. D. Howe and M. R. Cutkosky, "Sensing skin acceleration for texture and slip perception," *Proceedings of the 1989 IEEE Conference on Robotics and Automation*, Scottsdale, AZ, May 14-16, 1989.
5. M. R. Cutkosky and R. D. Howe, "Dynamic tactile sensing," *RoManSy 7: Seventh CISM-IFTOMM Symposium on the Theory and Practice of Robots and Manipulators*, Udine, Italy, September 12-15, 1988, A. Morecki, G. Bianchi, and K. Jaworek, eds., Editions Hermes, Paris, 1990.
4. R. D. Howe, I. Kao, and M. R. Cutkosky, "The sliding of robot fingers under combined torsion and shear loading," *Proceedings of the 1988 IEEE Conference on Robotics and Automation*, Philadelphia, PA, April 25-29, 1988.
3. M. R. Cutkosky, R. D. Howe, and A. P. Witkin, "Object-oriented modeling of robot hands," in *Symposium on Knowledge-Based Expert Systems for Manufacturing*, PED vol. 24, Lu, S. C-Y. and Komanduri, R., eds., American Society of Mechanical Engineers Winter Annual Meeting, Anaheim, CA, December 1986.
2. G. Kychakoff, R. K. Hanson, and R. D. Howe, "Simultaneous multiple-point measurements of oh in combustion gases using planar laser-induced fluorescence," *Proceedings of the 20th International Symposium on Combustion*, The Combustion Institute, pp. 1265-1272, 1985.

1. G. Kychakoff, R. D. Howe, and R. K. Hanson, "Use of planar laser-induced fluorescence for the study of combustion flowfields," paper 83-1361, 19th American Institute of Aeronautics and Astronautics Propulsion Conference, Seattle, WA, June 27-29, 1983.

Contributed Conference Papers, Abstracts, and Presentations

105. Liu Z, Howe R, 2022, October. "Friction Variability and Sensing Capabilities for Data-Driven Slip Detection: *The role of uncertainty and how it is tackled in robotic grasping and manipulation*" IEEE/RSJ International Conference on Intelligent Robots and Systems Workshop (IROS 2022) Kyoto, Japan.
104. Koenig A, Liu Z, Janson L, Howe R, "Tactile Sensing and its Role in Learning and Deploying Robotic Grasping Controllers," Workshop on Reinforcement Learning for Contact-Rich Manipulation, IEEE International Conference on Robotics and Automation (ICRA), May 23-27 2022, Philadelphia.
103. Liu Z, Howe RD, "Overlooked Variables in Compliant Grasping and Manipulation," Workshop on Compliant Robot Manipulation: Challenges and New Opportunities, IEEE International Conference on Robotics and Automation (ICRA), May 23-27 2022, Philadelphia.
102. Nuckols RW, Lee S, Swaminathan K, Walsh CJ, Howe RD, Sawicki GS, "Ultrasound Imaging of Plantarflexor Muscles During Robotic Ankle Assisted Walking: Effects on Muscle Tendon Dynamics and Application Towards Improved Exoskeleton and Exosuit Control," International Symposium on Wearable Robotics, Oct. 13, 2020, pp. 419-423, Springer, Cham.
101. Aktas B, Ornellas S, Narang YS, Vlassak J, Howe RD "Stiff-Soft Transitioning Wrist Brace Using Composite Layer Jamming" Workshop on Opportunities and Challenges in Soft Robotics Across Length Scales, International Conference on Robotics and Automation (ICRA), Montreal, Canada, May 20-24, 2019.
100. Nuckols RW, Swaminathan K, Lee S, Revi DA, Walsh CJ, Howe RD, "Investigating the role of muscle dynamics in individual response to soft exosuit assistance," Workshop on Human movement science for physical human-robot collaboration, International Conference on Robotics and Automation (ICRA), Montreal, Canada, May 20-24, 2019.
99. Swaminathan K, Lee S, Nuckols RW, Revi DA, Singh P, Howe RD, Smith MA, Walsh CJ, "Biomechanics Underlying Subject-Dependent Variability in Motor Adaptation to Soft Exosuit Assistance," In Masia L, Micera S, Akay M, Pons J (eds), *Converging Clinical and Engineering Research on Neurorehabilitation III: Proc. International Conference on NeuroRehabilitation*, Pisa, Italy, Oct. 2018, Biosystems & Biorobotics vol. 21, Springer.
98. Nuckols RW, Lee S, Revi DA, Degirmenci A, Walsh CJ, Howe R. Comparison of Subject-Specific Exosuit Assistance Profiles to Ultrasound Measurements of Gastrocnemius Fascicle Dynamics During Human Walking. The 8th World Congress of Biomechanics (WCB). 2018.
97. Nuckols RW, Lee S, Revi DA, Degirmenci A, Walsh C, Howe RD. "Evaluating Muscle Response to Exosuit Assistance", Dynamic Walking, May 21-25, 2018.
96. Saeed MY, Shin B, Payne CJ, Narang YS, Perrin D, Howe RD, Vasilyev, N, Ad N, del Nido PJ. "Innovative Minimal Invasive Technology for Epicardial Ventricular Ablation". AATS Annual Meeting. San Diego, CA, April 28-May 1, 2018.
95. Howe RD, "Combining Tactile Sensing and Grasp Analysis to Predict Grasp Stability," Workshop on Tactile Sensing for Manipulation: Hardware, Modeling, and Learning, RSS Conference, Cambridge, July 15, 2017.

94. Howe RD, "Achieving Selective Kinematics and Stiffness in Flexible Robotics," Robotics: Science and Systems Program Committee Meeting, Carnegie Mellon University, Pittsburgh, April 6, 2017
93. Wan Q, Howe RD, "Setting Realistic Expectations for Data-Driven Grasp Stability Prediction," Workshop on Empirically Data-Driven Manipulation, RSS 2017, Cambridge, USA, July 16, 2017
92. Qan Q, Howe RD, "On the Variability of Tactile Signals During Grasping," *Proceedings of the Australasian Conference on Robotics and Automation*, December 2-4, Canberra, Australia, <http://www.araa.asn.au/conferences/acra-2015/>
91. Degirmenci A, Walsh CJ, Hammond III FL, Wood RJ, Gafford JB, and Howe RD, "Design and Control of a Robotic System for Microsurgery," New England Manipulation Symposium (NEMS), Northeastern University, Boston, May 22, 2015.
90. Wan, Q, Howe, RD "Contact sensing based error detection in data-driven grasping," New England Manipulation Symposium (NEMS), Northeastern University, Boston, May 22, 2015.
89. Jentoft, L, Wan, Q, Howe, RD "How to Think About Designing and Controlling Robot Hands" New England Manipulation Symposium (NEMS), Columbia University, New York, NY, May 22, 2014.
88. Fu Q, Ushani A, Jentoft L, Howe RD, Santello, M. "Human reach-to-grasp compensation with object pose uncertainty," *Proceedings of the 35th Annual International Conference of the IEEE Engineering in Medicine and Biology Society*, July 3-7, 2013, pp. 6893-6896.
87. Tenenholtz NA, Howe RD, "Training Predictive Skills for Mitral Valve Repair." *Proceedings of the ASME/FDA 2013 Annual Frontiers in Medical Devices: Applications of Computer Modeling and Simulation*. Washington, DC, September 10-12, 2013.
86. Tenenholtz NA, Howe RD, "Developing a Training Tool for Intraoperative Mitral Valve Analysis." In 2013 Hamlyn Symposium on Medical Robotics. 2013.
85. Hammond III FL, Talbot SG, Wood RJ, Howe RD, "Measurement System for the Characterization of Micromanipulation Motion and Force," *Proceedings of the 2013 Design of Medical Devices Conference*, Minneapolis, MN April 8-11, 2013.
84. Howe RD, "Why 3D Ultrasound Isn't the Default Image Guidance Modality – and Why it Should Be," *Symposium on Surgical Robotics, Fourth IEEE RAS/EMBS International Conference on Biomedical Robotics and Biomechatronics (BioRob)*, Rome, June 24, 2012.
83. Jentoft LP, Howe RD, "Force Sensing with Compliant Joints," *Workshop on Advances in Tactile Sensing and Touch based Human-Robot Interaction, Human Robot Interaction 2012*, Boston, MA March 5–8, 2012.
82. Yeow CH, Baisch AT, Howe RD, Talbot SG, and Walsh CJ, "Differential Spring Stiffness Design for Finger Therapy Exercise Device: Bio-inspired from Stiff Pathological Finger Joints, *Proceedings of the 2012 Design of Medical Devices Conference*, Minneapolis, MN April 10-12, 2012, *ASME Journal of Medical Devices* 6: 017538-1.
81. Hammond III, Frank L., Simon G. Talbot, Robert J. Wood, and Robert D. Howe. "Data-Driven Design of a Dexterous Robotic Microsurgery System." *Proceedings of the 2012 Design of Medical Devices Conference*, Minneapolis, MN April 10-12, 2012, *ASME Journal of Medical Devices* 6(1).
80. Tenenholtz NA, Hammer PE, Howe RD, "Fast Interactive Simulations of Mitral Valve Repair," *Proc of 4th Annual International Conference in Computational Surgery and Dual Training*, Boston, Dec. 9-11, 2012.
79. Hammer PE, Howe RD, del Nido PJ, "Lower Transient Stresses in an Aortic Valve Leaflet with Oblique Reinforcement Fibers: a Finite Element Study," *Proceedings of the ASME 2012 Summer Bioengineering Conference (SBC2012)*, Fajardo, Puerto Rico, June 20-23, 2012.
78. Kesner SB, Jentoft LP, Hammond III FL, Howe RD, and Popovic M, "Design Considerations for an Active Soft Orthotic System for Shoulder Rehabilitation," *Proceedings of the 33rd Annual*

- International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC '11), Boston, August 30-Sept. 3, 2011, pp. 8130-34.
77. Jentoft L and Howe RD, "Compliant Fingers Make Simple Sensors Smart," International Workshop on Underactuated Grasping, Montreal, Canada, August 19, 2010.
 76. Howe RD, "Motion compensation for ultrasound-guided robotic heart surgery," Workshop on Enabling Technologies for Image-Guided Robotic Interventional Procedures, Robotics: Science and Systems Conference, Zaragoza, Spain, June 28, 2010.
 75. Howe RD, "Insights from Minimalism," Workshop on Grasp Acquisition: How to Realize Good Grasps, Robotics: Science and Systems Conference, Zaragoza, Spain, June 27, 2010.
 74. Hammer PE, Sacks MS, del Nido PJ, Howe RD. "Mass-Spring vs. Finite Element Models of Anisotropic Heart Valves: Speed and Accuracy," ASME 2010 Summer Bioengineering Conference, Naples, Florida, June 16-19, 2010, SBC2010-19521, pp. 149-50.
 73. Howe RD, "Fixing the Beating Heart: Ultrasound Guidance for Robotic Intracardiac Surgery," in Ayache N, Delingette H and Sermesant M, eds., *Proceedings of the 5th International Conference on Functional Imaging and Modeling of the Heart*, Springer Lecture Notes in Computer Science vol. 5528, Nice, France, June 3-5, 2009, pp. 97-103.
 72. Yuen SG, Kesner SB, and Howe RD, "A Robotic Surgical System for Beating-Heart Procedures, CIMIT Innovation Congress, Boston, MA, Oct 28-29, 2008. (Best Student Poster Award)
 71. Dollar AM and Howe, RD, "Simple, reliable robotic grasping for human environments," *Proceedings of the IEEE International Conference on Technologies for Practical Robot Applications (TePRA)*, Woburn, MA, USA, Nov. 10-11 2008, pp. 156-161.
 70. Tavakoli M and Howe RD, "Improving teleoperation performance in the presence of non-ideal robot dynamics," *Proceedings of the IEEE International Conference on Technologies for Practical Robot Applications (TePRA)*, Woburn, MA, USA, Nov. 10-11 2008, pp. 128-130.
 69. Jordan P, Socrate S, Zickler TE, Howe RD, "Enhanced Mechanical Characterization of Tissue Response Using Full-Field Deformation Data from 3D Ultrasound," Symposium on Non-Invasive Diagnostics for Biomechanics, 45th Annual Technical Meeting of the Society of Engineering Science, University of Illinois Urbana-Champaign, October 12-15, 2008.
 68. Dollar AM, Howe RD, "The SDM Hand: A Highly Adaptive Compliant Grasper for Unstructured Environments," in Khatib O, Kumar V, and Pappas GJ, *Proceedings of the 11th International Symposium on Experimental Robotics 2008 (ISER '08)*, Springer Tracts in Advanced Robotics, vol. 54, Athens, Greece, July 14-17, 2008, pp. 3-11.
 67. Tavakoli M, Howe RD, "Haptic Implications of Tool Flexibility in Surgical Teleoperation," *Proceedings of the 16th International Symposium on Haptic Interfaces for Virtual Environment & Teleoperator Systems*, IEEE Computer Society Press, March 13-14, 2008, Reno, Nevada, pp. 377-8.
 66. Howe RD, "Robo-surgeon: Combining medical imaging and mechanical models to automate surgery," Keynote address, SPIE Medical Imaging Conference, San Diego, February 18, 2008.
 65. Hammer PE, Perrin DP, del Nido PJ, Howe RD, "Image-Based Mass-Spring Model of Mitral Valve Closure for Surgical Planning," SPIE Medical Imaging, San Diego, February 2008, Proc. SPIE Vol. 6918, in press.
 64. Jordan P, Socrate S, Howe RD, "Image-based mechanical characterization of porcine liver using 3D ultrasound," Second International Conference on Mechanics of Biomaterials & Tissues, Kauai Hawaii, USA, December 9-13, 2007.
 63. P. Deckers, A.M. Dollar, and R.D. Howe, "Guiding Grasping with Proprioception and Markov Models," Manipulation Workshop: Sensing and Adapting to the Real World, Robotics: Science and Systems Conference, Atlanta, GA, June 30, 2007.

62. Kerdok AE, Howe RD, Socrate S, "Viscoelastic Characterization of Perfused Liver: Indentation Testing and Preliminary Modeling," to be presented at the ASME 2007 Summer Bioengineering Conference, Keystone, Colorado, USA, 20-24 June 2007.
61. Diamond, S.G., Howe, R.D., Schaechter, J.D., "Effect of hypnosis on motor function and cortical activation in chronic stroke patients," 13th Annual Meeting of the Organization for Human Brain Mapping (OHBM), Chicago, June 10-14, 2007.
60. Dollar AM, Howe RD, "A Simple, Robust Grasping in Unstructured Environments," Third Annual New England Manipulation Symposium (NEMS), Rensselaer Polytechnic Institute, Troy, NY, June 1, 2007.
59. Y. Ishihara, R. Nezafat, J.V. Wylie, M.G. Linguraru, M.E. Josephson, R.D. Howe, W.J. Manning, D.C. Peters, "3D Visualization of RF ablation scarring using delayed enhanced MRI co-registered with MRA," Joint Annual Meeting of the International Society for Magnetic Resonance in Medicine & the European Society for Magnetic Resonance in Medicine and Biology, Berlin, 19-25 May 2007.
58. Ottensmeyer MP, Kerdok AE, Socrate S, Howe RD "Mechanical Characterization of Artificially Perfused Porcine Liver," Symposium on Computer Simulation in Medicine (CompMed), Montreal, May 16-18, 2007.
57. Dollar AM and Howe RD, "Simple, Robust Grasping for Human Environments," Workshop on Technical Challenges for Dependable Robots in Human Environments, International Advanced Robotic Program, Rome, April 14-15, 2007.
56. Dollar AM and Howe RD, "Simple, Robust Autonomous Grasping in Unstructured Environments," Workshop on Contact Interface in Robotic Manipulation, 2007 IEEE International Conference on Robotics and Automation, Rome, April 14, 2007.
55. S. Yuen, D. Rudoy, R.D. Howe, P.J. Wolfe, "Switching Regressions for Bayesian Change-point Analysis in Material Indentation Experiments," New England Statistics Symposium, Worcester, Massachusetts, April 21, 2007.
54. Y. Ishihara, R. Nezafat, J.V. Wylie, M.G. Linguraru, M.E. Josephson, R.D. Howe, W.J. Manning, D.C. Peters, "MRI Evaluation of RF Ablation Scarring for Atrial Fibrillation Treatment," *Visualization and Image-Guided Procedures, Proceedings of SPIE* vol. 6509, K.R. Cleary and M.I. Miga, eds., San Diego Feb. 17 – 22, 2007.
53. Novotny, PM, Kettler, DT, Jordan, P, Dupont, PE, Del Nido, PJ, and Howe, RD, "Stereo Display of 3D Ultrasound Images for Surgical Robot Guidance," *Proceedings of the 28th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC)*, Aug 30-Sept. 3, 2006, New York, pp. 1509 - 1512.
52. Nakatani N, Howe RD, Tachi S, "The Fishbone Tactile Illusion," *Proceedings of EuroHaptics*, Paris, July 3-6, 2006.
51. Linguraru MG and Howe RD. "Texture-based Segmentation of Instruments in 3D Ultrasound," In EL Siegel, E Krupinski, and M Sonka, editors, *Medical Imaging, Proceedings of SPIE* vol. 6144, paper 6144J, 2006.
50. Vasilyev, NV, Novotny, PM, Martinez, JF, Roy, N, Salgo, IS, Howe, RD, Del Nido, PJ, "Stereo Vision Technology in Real-Time Three-Dimensional Echocardiography-Guided Intracardiac Beating-Heart Surgery," Proc. 9th Annual Scientific Meeting of International Society For Minimally Invasive Cardiothoracic Surgery, 2006.
49. Perrin DP, Wagner CR, Geisse N, Howe RD, Parker KK, "Haptic Interface for Cardiac Cell Exploration Using AFM," World Haptics Conference (First Joint Eurohaptics Conference and Symposium on Haptic Interfaces For Virtual Environment and Teleoperator Systems), Pisa, Italy, March 18-20, 2005.

48. Novotny PM, Dupont PE, Savord B, Salgo IS, Suematsu Y, Triedman J, Marx G, Del Nido PJ, Howe RD, "Guiding Robotic Surgery with 3D Ultrasound: A Study of Instrument Size on Surgical Performance," Medical Image Computing and Computer-Assisted Intervention - MICCAI, 2005.
47. Jordan P, Zickler T, Socrate S, Howe RD. "Non-Rigid Soft Tissue Tracking with Three-Dimensional Ultrasound." 4th International Conference on the Ultrasonic Measurement and Imaging of Tissue Elasticity. Austin, TX, 2005.
46. Kerdok AE, Jordan P, Liu Y, Wellman PS, Socrate S, Howe RD. "Identification of Nonlinear Constitutive Law Parameters of Breast Tissue." Proceedings of the 2005 Summer Bioengineering Conference. ASME, 2005.
45. Jordan P, Kerdok AE, Socrate S, Howe RD. "Breast Tissue Parameter Identification for a Nonlinear Constitutive Model." BMES Annual Fall Meeting. Baltimore, MD, 2005.
44. Linguraru, MG, Novotny, PM, Howe, RD, "Enhancement of Instrument Appearance in Ultrasound Images by Distribution and Spatial Analysis," Medical Image Computing and Computer-Assisted Intervention - MICCAI, 2005.
43. C.R. Wagner and R.D. Howe, "Embedded Strain Gage Force Sensor for Robotic Surgery," World Haptics Conference (First Joint Eurohaptics Conference and Symposium on Haptic Interfaces For Virtual Environment and Teleoperator Systems), Pisa, Italy, March 18-20, 2005.
42. Perrin DP, Ladd AM, Kavraki LE, Howe RD, Cannon JW, "Fast intersection checking for parametric deformable models," Medical Imaging 2005: Image Processing. San Diego, CA, Proceedings of SPIE 5747(1): 1468-74, February 17 2005.
41. Novotny, PM, Linguraru, MG, Marx, G, Del Nido, PJ, Howe, RD, *Using Real-Time Three-Dimensional Ultrasound to Characterize Mitral Valve Motion*, Proc. Biomedical Engineering Society - BMES, 2005.
40. Y. Suematsu, G.R Marx, J.A. Stoll, P.E. Dupont, R.D. Howe, J.K. Triedman, T. Mihaljevic, B.N. Mora, B.J. Savord, I.S. Salgo, and P.J. Del Nido, "3-Dimensional Echo Guided Beating-Heart Surgery Without Cardiopulmonary Bypass: Feasibility Study," American Association for Thoracic Surgery, Toronto, April 25 - 28, 2004.
39. P.M. Novotny, J.W. Cannon, and R.D. Howe, "Tool Localization in 3D Ultrasound Images," in R.E. Ellis and T.M. Peters, eds., *Proceedings of Medical Image Computing and Computer-Assisted Intervention - MICCAI 2003: 6th International Conference*, Montréal, Canada, November 15-18, 2003, Springer Lecture Notes in Computer Science, vol. 2879, part II, pp. 969-970.
38. A.M. Galea, and R.D. Howe, "Tissue stiffness from tactile imaging," *Proceedings of the Second Joint EMBS-BMES Conference*, IEEE Press, Vol. 2, pp. 935-6, October 23-26 2002.
37. J. W. Cannon, R. D. Howe, and P. J. del Nido, "Modeling Myocardial Injury During Trans-Atrial Intracardiac Procedures," *Medicine Meets Virtual Reality*, Newport Beach, California, Jan. 23-26, 2002.
36. H. E. Gunter, R. D. Howe, R. E. Hillman, and K. N. Stevens, "Analysis of factors affecting vocal fold impact stress using a mechanical model," Acoustical Society of America Annual Meeting, Fort Lauderdale, Florida, December 3-7, 2001.
35. J. Stoll, P. Dupont, R. Howe, R. Kikinis, and F. Jolesz, "Ultrasound-based Servoing of Manipulators during Telesurgery," in M. R. Stein, ed., *Telemanipulator and Telepresence Technologies VIII*, Newton, Massachusetts, 28 October – 2 November 2001, *Proceedings of SPIE* vol. 4570, p. 78-85.19. S. Selha, P. Dupont, R. D. Howe, and D. F. Torchiana, "Dexterity Optimization in Robot-Assisted Minimally Invasive Surgery," in M. R. Stein, ed., *Telemanipulator and Telepresence Technologies VIII*, Newton, Massachusetts, 28 October – 2 November 2001, *Proceedings of SPIE* vol. 4570, p. 97-104.

34. T. Debus, T.-J. Jang, P. Dupont and R. Howe, "A Multi-channel Vibrotactile Display for Sensory Substitution During Teleoperation," in M. R. Stein, ed. *Telemanipulator and Telepresence Technologies VIII*, Newton, Massachusetts, 28 October – 2 November 2001, *Proceedings of SPIE* vol. 4570, p. 42-49.
33. T. Debus, J. Stoll, R. D. Howe, and P. Dupont, "Cooperative Human and Machine Perception in Teleoperated Assembly" in D. Rus and S. Singh, eds., *Experimental Robotics VII. The Fifth International Symposium*, Honolulu, HI, December 10-13, 2000, Springer Lecture Notes in Control and Information Sciences, pp. 51-60, 2001.
32. Y. Matsuoka and R. D. Howe, "Hand Impedance Change During Learning of a Novel Contact Task," 2000 World Congress on Medical Physics and Biomedical Engineering, Chicago, July 23-28, 2000,
31. P. S. Wellman, R. D. Howe, N. Dewagan, M. A. Cundari, E. Dalton, K. A. Kern, "Tactile Imaging: A Method for Documenting Breast Masses," *Proceedings of the First Joint BMES/EMBS Conference*, Atlanta, Oct. 13-16, 1999, p. 1131.
30. D.T.V. Pawluk, R.D. Howe, "Dynamic Contact Mechanics of the Human Fingerpad with a Flat Surface," Biomedical Engineering Society Annual Meeting, Cleveland, October 11 , 1998.
29. R. D. Howe, T. Debus and P. Dupont, "Haptic Identification of Remote Environment Properties," *Telemanipulator and Telepresence Technologies V*, M. R. Stein, ed., *Proceedings of SPIE* Vol. 3524, Boston, November 4-5, 1998, pp. 123-130.
28. J.S. Kimmelman, J.T. Dennerlein, R.D. Howe. Fingertip pressure distribution during pinch and lift tasks. International Mechanical Engineering Conference and Exhibition of the American Society of Mechanical Engineering (ASME), Bioengineering Division, Anaheim, CA, 1998. (Best Undergraduate Student Paper Award)
27. R. D. Howe, D. A. Kontarinis, W.J. Peine, and P. W. Wellman, "Tactile displays for increased spatial and temporal bandwidth in haptic feedback," in Y. Shirai and S. Hirose, eds., *Robotics Research: The Eighth International Symposium*, October 4-7, 1997, Hayama, Japan, Springer-Verlag, Berlin, 1998.
26. D. T. V. Pawluk and R. D. Howe, "Contact pressure distribution on the human finger pad," 26th Congress of the International Society of Biomechanics, Tokyo, August 25-29, 1997, p. 335.
25. Pawluk, D.T.V., Peine, W.J., Wellman, P.S. and Howe, R.D., "Simulating Soft Tissue with a Tactile Shape Display," ASME International Mechanical Engineering Congress and Exposition, Dallas, Nov. 15-21, 1997, in B. Simon, ed., *Advances in Bioengineering*, ASME BED-Vol. 36, pp. 253-4.
24. P.S. Wellman and R.D. Howe, "Modeling probe and tissue interaction for tumor feature extraction," 1997 ASME Summer Bioengineering Conference, Sun River, OR., June 1997, BED-Vol. 35, pp. 237-8.
23. D. T. V. Pawluk and R. D. Howe, "Mechanical impedance and energy dissipation in the human finger pad," 1997 ASME Summer Bioengineering Conference, Sun River, Oregon, June 1997, BED-Vol. 35, p. 591-592.
22. W.J. Peine and R. D. Howe, "Finger pad shape in lump detection," 1997 ASME Summer Bioengineering Conference, Sun River, Oregon, June 1997, BED-Vol. 35, p. 593-594.
20. P.S. Wellman, W.J. Peine, G. Favalora, and R. D. Howe, "Mechanical Design and Control of a High-Bandwidth Shape Memory Alloy Tactile Display," in A. Casals and A.T. de Almeida, eds., *Experimental Robotics V. The Fifth International Symposium*, Barcelona, Spain, June 15-18, 1997, Springer Lecture Notes in Control and Information Sciences vol. 232, pp. 56-66.
19. Pawluk D. and Howe, R.. A Holistic Model of Human Touch. In J.M. Bower (Ed.) *Computational Neuroscience Trends in Research* (Proceedings of the Fifth Annual Computational Neuroscience Conference, Cambridge, MA, July 14-17, 1996) Plenum Press, New York, pp. 759-764, 1997.

18. R. D. Howe, "Robotic skin sensors and contact mechanics signal analysis," Workshop on the Role of Tissue Mechanics on Somatosensation, Institute for Sensory Research, Syracuse University, Syracuse, N.Y., June 1996.
17. A. Z. Hajian and R. D. Howe, "Variation of finger tip impedance in pinch grip," 9th Engineering Foundation Conference on Biomechanics & Neural Control of Movement, Mt. Sterling, Ohio, June 1-6, 1996.
16. D. A. Kontarinis and R. D. Howe, "Tactile displays for dextrous telemanipulation," ECPD International Conference on Advanced Robotics and Intelligent Automation, Athens, Greece, September 6-8, 1995.
15. J. Son and R.D. Howe, "Performance limits and stiffness control of multifingered hands." O. Khatib and J.K. Salisbury, eds. *Experimental Robotics IV: The 4th International Symposium*, Stanford, June 30-July 2, 1995, Springer Lecture Notes in Control & Information Sciences vol. 223, 1997. pp. 91-102.
14. D. A. Kontarinis and R. D. Howe, "A multiparameter tactile display system for teleoperation," T.B. Sheridan, ed., *Analysis, Design and Evaluation of Man-Machine Systems 1995: Postprint volume from the Sixth IFAC/IFIP/IFORS/IEA Symposium*, Cambridge, June 27-29 1995, Pergamon Press, vol. 1, pp. 83-88.
13. D. A. Kontarinis and R. D. Howe, "Static display of shape," in H. Das, ed., *Telemanipulator & Telepresence Technologies*, Boston, MA, October 31-November 1, 1994, *Proc. SPIE* vol. 2351, pp. 250-9.
12. W.J. Peine, D. A. Kontarinis, R. D. Howe, "A remote palpation system for minimally invasive surgery," Society for Minimally Invasive Therapy 6th International Meeting, Berlin, Germany, October 2-4, 1994 (Best poster award).
11. D. A. Kontarinis and R. D. Howe, "Tactile display of contact shape in dextrous manipulation," in *Advances in Robotics, Mechatronics, and Haptic Interfaces*, DSC-vol. 49, H. Kazerooni, J. E. Colgate, and B. D. Adelstein, eds., American Society of Mechanical Engineers Winter Annual Meeting, New Orleans, Nov. 29-30, 1993, pp. 81-88.
10. R. D. Howe and D. A. Kontarinis, "High frequency force information in teleoperated manipulation," in T. Yoshikawa and F. Miyazaki, eds., *Experimental Robotics III: Proc. Third International Symposium on Experimental Robotics*, Kyoto, Japan, Oct. 28-30, 1993, Springer Lecture Notes In Control and Information Sciences vol. 200, 1994, pp. 343-352.
9. D. A. Kontarinis and R. D. Howe, "Display of high frequency tactile information to teleoperators," in W. Kim, ed., *Telemanipulator Technology and Space Robotics Conference*, Boston, MA, Sept. 7-9, 1993, *Proceedings of SPIE* vol. 2057, pp. 40-50.
8. R. D. Howe, "External friction models for robotic manipulation," Tutorial session, Friction in robotic assembly and manipulation, IEEE International Conference on Robotics & Automation, Atlanta, May 2-6, 1993.
7. R. D. Howe and D. Kontarinis, "Task performance with a dextrous teleoperated hand system," in H. Das, ed., *Telemanipulator Technology Conference*, Boston, MA, Nov. 15-16, 1992, *Proceedings of SPIE* vol. 1833, pp. 199-207.
6. R. D. Howe, B. B. Edin, M. R. Cutkosky and G. Westling, "Relaying friction information to a human operator for dextrous telemanipulation," SPIE Conference on Telerobotics: Cooperative Intelligent Robotics in Space, Boston, MA, November 12-14, 1991.
5. R. D. Howe and G. Kychakoff, "Low cost programmable correlator for industrial use," paper WI13, 1987 Conference on Lasers and Electrooptics, Baltimore, MD, April 27 - May 1, 1987.
4. R. D. Howe and G. Kychakoff, "Reflection-based fiber-optic displacement sensor," 5th international congress on Applications of Lasers and Electro-Optics, Arlington, VA, November 10-13, 1986.

3. R. D. Howe and G. Kychakoff, "Optical sensing system for thermoplastic composites forming," paper TUK48, 1986 Conference on Lasers and Electro-Optics, San Francisco, CA, June 9-13, 1986.
2. G. Kychakoff, R. D. Howe, R. K. Hanson, and K. Knapp, "Flow visualization in combustion gases using planar laser-induced fluorescence," paper No. 83-0405, American Institute of Aeronautics and Astronautics 21st Aerospace Sciences Meeting, Reno, NV, Jan. 1983.
1. G. Kychakoff, K. Knapp, R. D. Howe, and R. K. Hanson, "Quantitative flow visualization in combustion gases," paper No. 82-60, Meeting of the Western States Section of The Combustion Institute, Livermore, CA, Oct. 11-12, 1982.

Books and Book Chapters

7. Golland, P., Hata, N., Barillot, C., Hornegger, J., Howe, R, eds., *Proceedings of the 17th International Conference on Medical Image Computing and Computer-Assisted Intervention - MICCAI 2014*, Boston, September 14-18, 2014, vols. 1-3.
6. M.R. Cutkosky, R.D. Howe, W.R. Provancher, "Force and Tactile Sensors," Chapter 19, in B. Siciliano and O. Khatib, eds., *Springer Handbook of Robotics*, Springer, Berlin, 2008.
5. A. Z. Hajian and R. D. Howe, "Biomechanics of Manipulation: Grasping the Task at Hand," in J. Winters and P. Crago, eds, *Neural Control of Posture & Movement*, Springer-Verlag, 2000, pp.382-389.
4. W. J. Peine, D. A. Kontarinis, and R. D. Howe, "A tactile sensing and display system for surgical applications," in R. M. Satava et al., eds., *Interactive Technology and the New Paradigm for Healthcare*, Amsterdam, IOS Press, 1995.
3. R. D. Howe and M. R. Cutkosky, "Touch sensing for robotic manipulation and recognition," in O. Khatib et al., eds., *Robotics Review 2*, Cambridge, MIT Press, 1992, pp. 55-112.
2. M. R. Cutkosky and R. D. Howe, "Human grasp choice and robotic grasp analysis," in S. T. Venkataraman and T. Iberall, eds., *Dextrous Robot Hands*, New York, Springer-Verlag, 1990.
1. M. R. Cutkosky, P. Akella, R. D. Howe, and I. Kao, "Grasping as a contact sport," in R. Bolles and B. Roth, eds., *Robotics Research*, Cambridge, MIT Press, pp. 199-206, 1987.

Patents

- L. Odhner, L. Jentoft, Y. Tenzer, M. Keck, R. Howe, "Assessing robotic grasping," US Patent 11,338,436, issued May 24, 2022.
- L. Odhner, L. Jentoft, Y. Tenzer, M. Keck, R. Howe, "Training robotic manipulators," US Patent 11,173,602, issued November 16, 2021.
- S. Cheng, Y. Narang, C. Yang, Z. Suo, R. Howe, "Composite materials," US Patent application no. 16/872,088, filed May 11, 2020.
- L. Jentoft, Y. Tenzer, and R.D. Howe, "Method of Making a Contact Pressure Sensor," US Patent 10,488,284, issued November 26, 2019.
- J. Aizenberg, M. Kolle, P. Vukusic, R.D. Howe, "Band-gap tunable elastic optical multilayer fibers," US Patent 10,146,007, Dec. 4, 2018.
- L. Jentoft, Y. Tenzer, and R. Howe, "Tactile sensor," US Patent 9,625,333, April 18, 2017.
- S. Kesner, R. Howe, S. Yuen, P. del Nido, D. Perrin, and N. Vasilyev, "Motion compensating catheter device," patent application WO2011137336, filed April 29, 2011.
- A. Dollar and R.D. Howe, "Robust Compliant Adaptive Grasper and Method of Manufacturing Same," US Patent 8,231,158, July 31, 2012.
- D.P. Perrin and R.D. Howe, "Actuated tether," US Patent 7,255,192, August 14, 2007.

P.S. Wellman, J.S. Son, R.D. Howe, "System generating a pressure profile across a pressure sensitive membrane," U.S. Patent No. 5,983,727, November 16, 1999.

R.D. Howe and G. Kychakoff, "Fiber-optic Inverse-square Displacement Sensor," US Patent 4,865,443, September 12, 1989.

Other Publications and Presentations

"Tactile Feedback in Telemanipulation," *Video proceedings of the IEEE International Conference on Robotics & Automation*, New Orleans, April, 2004.

"Modeling by Manipulation" *Video proceedings of the IEEE International Conference on Robotics & Automation*, New Orleans, April, 2004.

"Robotic Surgery – The Healing Touch," video exhibit, Museum of Science, Boston.

R. D. Howe and R. E. Kronauer, "Thomas McMahon: A Dedication In Memoriam," *Annual Review of Biomedical Engineering* vol. 3, 2001.

"Robots, surgery, and the sense of touch," Harvard University Science Center Research Lecture, April 19, 1995.

Invited testimony, Hearing on the Future of Research-Intensive Universities and Their Relationship with the Federal Government, President's Council of Advisors on Science and Technology, Dr. D. Allan Bromley, Chair, Massachusetts Institute of Technology, June 24, 1992.

Expert Witness Experience: Depositions, Trial Testimony, and IPR Declarations

Robert D. Howe

January 2023

Restore Robotics LLC and Restore Robotics Repair LLC v. Intuitive Surgical, Inc.

No. 5:19-cv-55-TKW-MJF, Northern District of Florida

Testified at deposition for Intuitive Surgical (defendant, represented by Skadden, Arps, Slate, Meagher & Flom LLP). October 2021.

Rebotix Repair LLC v. Intuitive Surgical, Inc.

No. 8:20-cv-2274-T-33TGW, Middle District of Florida

Testified at deposition for Intuitive Surgical (defendant, represented by Skadden, Arps, Slate, Meagher & Flom LLP). October 2021.

Rex Medical, L.P. v. Intuitive Surgical, Inc.

No. 19-cv-00005-MN, District of Delaware

Testified at deposition and trial for Intuitive Surgical (defendant, represented by Winston & Strawn). Tried October 2022.

Ethicon LLC v. Intuitive Surgical, Inc.

No. 17-871-LPS-CJB, District of Delaware

Testified at ITC evidentiary hearing for Intuitive Surgical (defendant, represented by Kecker, Van Nest & Peters). Feb. 2021.

Immersion Corporation v. Samsung Electronics America, Inc. and Samsung Electronics Co., Ltd.

No. 2:17-cv-00572-JRG, Eastern District of Texas

Testified at deposition for Immersion Corporation (plaintiff, represented by Morrison & Foerster). 2018-2019.

Immersion Corporation v. Motorola Mobility LLC and Motorola Mobility Holdings LLC

No. 17-1081-RGA, District of Delaware

Testified at deposition for Immersion Corporation (plaintiff, represented by Morrison & Foerster). 2018-2019.

Zenimax Media Inc. and Id Software LLC v. Oculus VR LLC, Facebook Inc., et al.

No. 3:14-CV-01849, Northern District of Texas

Testified at deposition and trial for Oculus VR LLC, Facebook Inc., et al. (defendants, represented by Cooley), tried January 2017.

Appendix B

List of Materials Considered

Produced Documents

(In re: da Vinci Surgical Robot Antitrust Litigation, Case No. 3:21-cv-03825-VC and Surgical Instrument Service Co. v. Intuitive Surgical, Inc., Case 3:21-cv-03496-VC):

- Intuitive-00004685
- Intuitive-00004692
- Intuitive-00008958
- Intuitive-00010744
- Intuitive-00010745
- Intuitive-00027876
- Intuitive-00043879
- Intuitive-00104966
- Intuitive-00223998
- Intuitive-00290857
- Intuitive-00369329
- Intuitive-00477154
- Intuitive-00477217
- Intuitive-00477325
- Intuitive-00477422
- Intuitive-00477597
- Intuitive-00477620
- Intuitive-00477757
- Intuitive-00477829
- Intuitive-00477958
- Intuitive-00478097
- Intuitive-00537574
- Intuitive-00538487
- Intuitive-00538913
- Intuitive-00538994
- Intuitive-00539807
- Intuitive-00544186
- Intuitive-00544195
- Intuitive-00544197
- Intuitive-00544198
- Intuitive-00544199
- Intuitive-00544388
- Intuitive-00544456
- Intuitive-00544494
- Intuitive-00546343
- Intuitive-00546380
- Intuitive-00546920

- Intuitive-00547846
- Intuitive-00551503
- Intuitive-00552529
- Intuitive-00552535
- Intuitive-00552744
- Intuitive-00552744
- Intuitive-00552745
- Intuitive-00589150
- Intuitive-00597660
- Intuitive-00603411
- Intuitive-00620947
- Intuitive-00626429
- Intuitive-00626673
- Intuitive-00695006
- Intuitive-00705141
- Intuitive-00705143
- Intuitive-00705155
- Intuitive-00705253
- Intuitive-00705351
- Intuitive-00705406
- Intuitive-00705431
- Intuitive-00705438
- Intuitive-00705453
- Intuitive-00784474
- Intuitive-01085065
- Intuitive-01085533

Produced Documents (Restore/Rebotix):

- ACG000006
- AHP000369
- AHP000373
- AHP000404
- AHP000525
- AHP000527
- AHP000658
- AHP000706
- AHP000708
- AHP000729
- AHP000732
- AHP000803

- AHP000832
- AHP000928
- AHP000939
- AHP002062
- AHP002130
- AHP002395
- AHP002448
- AHP002623
- AHP002680
- AHP003709
- AHP005099
- AHS_HMC-INTUITIVE_0000039
- AHS_MGMT000007
- AHS_MGMT-INTUITIVE_0000312
- AHS_MGMT-INTUITIVE_0000313
- AHS_MGMT-INTUITIVE_0000603
- BB000011
- BPI000331
- BSWH-0000221
- BSWH-0000255
- CRMC
- Intuitive-00552744
- Intuitive-00552745
- REBOTIX000365
- REBOTIX000664
- REBOTIX000874
- REBOTIX001027
- REBOTIX001045
- REBOTIX001068
- REBOTIX001338
- REBOTIX005360
- REBOTIX040844
- REBOTIX042756
- REBOTIX045741
- REBOTIX048397
- REBOTIX060630
- REBOTIX074051
- REBOTIX077238
- REBOTIX077440
- REBOTIX077446
- REBOTIX077536

- REBOTIX077545
- REBOTIX077549
- REBOTIX077597
- REBOTIX077601
- REBOTIX077611
- REBOTIX077617
- REBOTIX077671
- REBOTIX077729
- REBOTIX077735
- REBOTIX081884
- REBOTIX082118
- REBOTIX084174
- REBOTIX084240
- REBOTIX084679
- REBOTIX084983
- REBOTIX088383
- REBOTIX089889
- REBOTIX090153
- REBOTIX100995
- REBOTIX119844
- REBOTIX121303
- REBOTIX123447
- REBOTIX123792
- REBOTIX131417
- REBOTIX131427
- REBOTIX131433
- REBOTIX131437
- REBOTIX131480
- REBOTIX131484
- REBOTIX131488
- REBOTIX131493
- REBOTIX131501
- REBOTIX131514
- REBOTIX132017
- REBOTIX132018
- REBOTIX132063
- REBOTIX132064
- REBOTIX132131
- REBOTIX132132
- REBOTIX132133
- REBOTIX132176

- REBOTIX132177
- REBOTIX132244
- REBOTIX132245
- REBOTIX132288
- REBOTIX132289
- REBOTIX132356
- REBOTIX132357
- REBOTIX132399
- REBOTIX132400
- REBOTIX132455
- REBOTIX132456
- REBOTIX132495
- REBOTIX132496
- REBOTIX133038
- REBOTIX133043
- REBOTIX133235
- REBOTIX133239
- REBOTIX133272
- REBOTIX133279
- REBOTIX133344
- REBOTIX134641
- REBOTIX139107
- REBOTIX146770
- REBOTIX146948
- REBOTIX152284
- REBOTIX153047
- REBOTIX155864
- REBOTIX155894
- REBOTIX162404
- REBOTIX169166
- REBOTIX169167
- REBOTIX169168
- REBOTIX169360
- REBOTIX169504
- REBOTIX169588
- REBOTIX169683
- REBOTIX169926
- REBOTIX169947
- REBOTIX170053
- REBOTIX170421
- REBOTIX171030

- REBOTIX171058
- REBOTIX171073
- REBOTIX171076
- REBOTIX175327
- REBOTIX175417
- REBOTIX175419
- REBOTIX175421
- REBOTIX175447
- REBOTIX175468
- REBOTIX175710
- Restore-00086093
- Restore-00000917
- Restore-00001424
- Restore-00001538
- Restore-00002087
- Restore-00002095
- Restore-00002650
- Restore-00003205
- Restore-00004876
- Restore-00005217
- Restore-00005218
- Restore-00007128
- Restore-00007938
- Restore-00007942
- Restore-00007947
- Restore-00007976
- Restore-00007980
- Restore-00008152
- Restore-00008310
- Restore-00008312
- Restore-00008313
- Restore-00008320
- Restore-00008324
- Restore-00008325
- Restore-00008332
- Restore-00008339
- Restore-00008340
- Restore-00008341
- Restore-00008342
- Restore-00008343
- Restore-00008344

- Restore-00008345
- Restore-00008346
- Restore-00008347
- Restore-00008349
- Restore-00008350
- Restore-00008351
- Restore-00008352
- Restore-00008353
- Restore-00008354
- Restore-00008355
- Restore-00008356
- Restore-00008357
- Restore-00008358
- Restore-00008360
- Restore-00008362
- Restore-00008364
- Restore-00008365
- Restore-00008366
- Restore-00008367
- Restore-00008373
- Restore-00008377
- Restore-00008381
- Restore-00009030
- Restore-00010132
- Restore-00015116
- Restore-00015645
- Restore-00025590
- Restore-00025717
- Restore-00026026
- Restore-00026027
- Restore-00027410
- Restore-00030379
- Restore-00044908
- Restore-00060361
- Restore-00060362
- Restore-00060365
- Restore-00060739
- Restore-00060741
- Restore-00062443
- Restore-00062688
- Restore-00063245

- Restore-00063246
- Restore-00063284
- Restore-00063474
- Restore-00063595
- Restore-00063598
- Restore-00064367
- Restore-00064369
- Restore-00064384
- Restore-00064401
- Restore-00064403
- Restore-00064407
- Restore-00064566
- Restore-00067931
- Restore-00067983
- Restore-00086179
- Restore-00086907
- Restore-00086957
- Restore-00086959
- Restore-00087134
- Restore-00087136
- Restore-00087137
- Restore-00087138
- Restore-00087139
- Restore-00087140
- Restore-00087141
- Restore-00087166
- Restore-00087171
- Restore-00087177
- Restore-00087183
- Restore-00087187
- Restore-00087190
- Restore-00087191
- Restore-00087340
- Restore-00087343
- Restore-00087345
- Restore-00087348
- Restore-00087349
- Restore-00087364
- Restore-00087390
- Restore-00087394
- Restore-00087398

- Restore-00087401
- Restore-00087475
- Restore-00087477
- Restore-00087479
- Restore-00087482
- Restore-00087485
- Restore-00087507
- Restore-00087508
- Restore-00087524
- Restore-00087650
- Restore-00087652
- Restore-00087666
- Restore-00087679
- Restore-00087682
- Restore-00087688
- Restore-00087695
- Restore-00087721
- Restore-00087745
- Restore-00087773
- Restore-00087777
- Restore-00087781
- Restore-00087793
- Restore-00087799
- Restore-00087839
- Restore-00087852
- Restore-00087861
- Restore-00089433
- Restore-00089435
- Restore-00089437
- Restore-00089453
- Restore-00089461
- Restore-00089477
- Restore-00089478
- Restore-00089479
- Restore-00089490
- Restore-00089504
- Restore-00089513
- Restore-00089522
- Restore-00089529
- Restore-00089535
- Restore-00089537

- Restore-00089540
- Restore-00089541
- Restore-00089585
- Restore-00089590
- Restore-00089593
- Restore-00089599
- Restore-00089605
- Restore-00089606
- Restore-00089609
- Restore-00089694
- Restore-00089701
- Restore-00089708
- Restore-00089994
- Restore-00090617
- Restore-00095403
- Restore-00095407
- Restore-00095420
- Restore-00095430
- Restore-00095432
- Restore-00095453
- Restore-00095478
- Restore-00095533
- Restore-00095583
- Restore-00095608
- Restore-00095616
- Restore-00096294
- Restore-00099136
- Restore-00099137
- Restore-00099139
- Restore-00102436
- Restore-00103167
- Restore-00104982
- Restore-00104984
- Restore-00106446
- Restore-00106456
- Restore-00106457
- Restore-00106460
- Restore-00106463
- Restore-00106464
- Restore-00106470
- Restore-00106491

- Restore-00109056
- Restore-00109063
- Restore-00109203
- Restore-00112595
- Restore-00132582
- Restore-00132590
- Restore-00132591
- Restore-00132592

Deposition Transcripts and Exhibits

(In re: da Vinci Surgical Robot Antitrust Litigation, Case No. 3:21-cv-03825-VC and Surgical Instrument Service Co. v. Intuitive Surgical, Inc., Case 3:21-cv-03496-VC):

- Duque, Grant 30(b)(6) (Nov. 8, 2022) and Exhibits
- Goodson, Nickola (Oct. 27, 2022) and Exhibits
- Hamilton, Stan (Nov. 4, 2022) and Exhibits
- Johnson, Keith (Oct. 27, 2022) (individual testimony) and Exhibits
- Johnson, Keith 30(b)(6) (Oct. 27, 2022) and Exhibits
- May, Kevin (Nov. 3, 2022) and Exhibits
- Parker, Clifton (Oct. 25, 2022) and Exhibits
- Peswani, Disha (Oct. 6, 2022) and Exhibits
- Posdal, Greg (Nov. 1, 2022) (individual testimony) and Exhibits
- Posdal, Greg 30(b)(6) (Nov. 1, 2022) and Exhibits
- Somayaji, Sharathchandra (Nov. 4, 2022) and Exhibits

Deposition Transcripts and Exhibits

(Restore Robotics LLC v. Intuitive Surgical, Inc., Case No. 5:19-cv-55-TKW-MJF):

- Gordon, West (May 13, 2021) and Exhibits
- May, Kevin (May 6, 2021) and Exhibits
- May, Kevin (June 8, 2021) and Exhibits
- Parker, Clifton (May 4, 2021) and Exhibits
- Vautrot, Mills (May 11, 2021) and Exhibits

Expert Reports

(In re: da Vinci Surgical Robot Antitrust Litigation, Case No. 3:21-cv-03825-VC)

- Expert Report of Professor Einer Elhauge (Dec. 1, 2022)
- Expert Report of Dr. Eugene Rubach (Dec. 1, 2022)
- Expert Report of Kimberly A. Trautman, MS (Dec. 1, 2022)

Expert Reports

(Surgical Instrument Service Co. v. Intuitive Surgical, Inc., Case 3:21-cv-03496-VC)

- Expert Report of Richard F. Bero (Dec. 2, 2022)

- Expert Report of Dr. Russel L. Lamb (Dec. 2, 2022)
- Expert Report of Amandeep Mahal, MD (Dec. 1, 2022)
- Expert Report of Philip J. Philips (Dec. 2, 2022)

Court Documents

(In re: da Vinci Surgical Robot Antitrust Litigation, Case No. 3:21-cv-03825-VC)

- Consolidated Class Action Complaint (ECF. No 52)
- Defendant Intuitive Surgical, Inc.’s Answer and Affirmative Defense (ECF 74)
- Plaintiff Franciscan Alliance, Inc.’s Amended Objections and Responses to Defendant’s Second Set of Interrogatories to Plaintiffs (Sept. 30, 2022)
- Plaintiff Larkin’s Amended Objections and Responses to Defendant’s Second Set of Interrogatories to Larkin (Sept. 30, 2022)
- Plaintiff Valley Medical Center’s Amended Objections and Responses to Defendant’s Second Set of Interrogatories to Plaintiffs (Sept. 30, 2022)
- Plaintiff Franciscan Alliance, Inc.’s Objections and Responses to Defendant’s Requests for Admissions to Plaintiff (Nov. 16, 2022)
- Plaintiff Larkin Community Hospital’s Objections and Responses to Defendant’s Requests for Admissions to Plaintiff (Nov. 16, 2022)
- Plaintiff Valley Medical Center’s Objections and Responses to Defendant’s Requests for Admissions to Plaintiff (Nov. 16, 2022)

Court Documents

(Surgical Instrument Service Co. v. Intuitive Surgical, Inc., Case 3:21-cv-03496-VC):

- SIS Complaint (ECF No. 1)
- Defendant Intuitive Surgical, Inc.’s Answer, Affirmative Defenses, and Counterclaims (ECF No. 75)
- Plaintiff Surgical Instrument Service Company, Inc.’s Answers & Objections to Defendant’s Interrogatories, Second Set – Nos. 4-18 (Aug. 8, 2022)

Other Materials:

- “Access and instruments product catalog” Medtronic, 2020, available at: <https://www.medtronic.com/content/dam/covidien/library/us/en/product/handinstruments-and-ligation/access-instrumentation-products-catalog.pdf>.
- Anderson, James M., Analiz Rodriguez, and David T. Chang. “Foreign body reaction to biomaterials,” in *Seminars in Immunology*, vol. 20, no. 2, pp. 86-100, 2008
- August 19, 2021 Conversation with Ron Bair
- da Vinci S and Si Instrument Reprocessing Instructions for Automated Cleaning and Disinfection, https://manuals.intuitivesurgical.com/c/document_library/get_file?uuid=d237e175-3fce-3844-863e-37e733afe0d6&groupId=73750789
- da Vinci Xi Instrument Reprocessing Instructions for Automated Cleaning and Disinfection,

https://manuals.intuitivesurgical.com/c/document_library/get_file?uuid=b1b9f169-4503-9ea9-6db9-9243c28d5221&groupId=73750789

- Def.’s Ex. 135 (Defendant Intuitive Surgical Inc.’s Notice of Deposition of Plaintiff Surgical Instrument Service Company, Inc. Pursuant to Fed. R. Civ. P. 30(b)(6))
- Design Control Guidance for Medical Device Manufacturers, US Food and Drug Administration, available at: <https://www.fda.gov/media/116573/download>
- DS2505 Dallas Semiconductor data sheet, available at: <https://datasheets.maximintegrated.com/en/ds/DS2505.pdf>
- “Expanding the Reach of Surgery,” Medrobotics “Flex” brochure, available at: <https://www.easmed.com/main/wp-content/uploads/BROCHURE-Medrobotics-Transanaleasmed.pdf>
- Expert Report of Dr. Robert D. Howe (July 26, 2021) (served in *Rebotix*, Case 8:20-cv-02274-VMC-TGW) and materials cited therein
- Expert Report of Dr. Robert D. Howe (Aug. 20, 2021) (served in *Restore*, Civil Case No. 5:19-cv-55-TKW-MJF) and materials cited therein
- Expert Report of Dr. Robert D. Howe (Dec. 2, 2022) (served in *Surgical Instrument Service*, Case 3:21-cv-03496-VC) and materials cited therein
- Supplemental Expert Report of Dr. Robert D. Howe (Dec. 23, 2022) (served in *Restore*, Civil Case No. 5:19-cv-55-TKW-MJF) and materials cited therein
- “Flex Robotic System Technology: How it Works,” available at: <https://medrobotics.com/gateway/technology/>
- “Flexible ‘open architecture’ instrumentation,” available at: <https://medrobotics.com/gateway/instruments/>
- Intuitive Surgical, Inc., Annual Report 2021, <https://isrg.intuitive.com/static-files/704322bf-cb0d-4ed1-954c-8eb46a070f70>
- Koukourikis P, Rha KH. Robotic surgical systems in urology: What is currently available? *Investigative and Clinical Urology*. 2021
- Patient Side Cart (PSC) Setup Joint and Carriage Component Replacements (Intuitive-00705453)
- Richard G. Budynas and J. Keith Nisbett, *Shigley’s Mechanical Engineering Design*, Ninth Edition, McGraw-Hill, New York, 2008
- [Senhance.com/indications](https://senhance.com/indications)
- Senhance Surgical System EMEA Product Catalog, January 2020
- Truscott, Wava. “Impact of Microscopic Foreign Debris on Post-Surgical Complications,” in *Surgical Technol. Int’l*, vol. 12:34-46, 2004
- U.S. Food and Drug Admin., Manufacturer and user facility device experience database – (Maude), <https://www.fda.gov/medical-devices/mandatory-reporting-requirementsmanufacturers-importers-and-device-user-facilities/manufacture-and-user-facilitydevice-experience-database-maude>
- U.S. Navy Wire-Rope Handbook, Vol. 1
- US Patent No. 5,797,900
- US Patent No. 6,991,627

- Wang, Cecily F., James Cipolla, Mark J. Seamon, David E. Lindsey, and S. Peter Stawicki. “Gastrointestinal complications related to retained surgical foreign bodies (RSFB): A concise review,” in OPUS 12:11-8, 2007

Exhibit 5

1 Kenneth A. Gallo (*pro hac vice*)
2 Paul D. Brachman (*pro hac vice*)
3 **PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP**
4 2001 K Street, NW
5 Washington, DC 20006-1047
6 Telephone: (202) 223-7300
7 Facsimile: (202) 204-7420
8 Email: kgallo@paulweiss.com
9 Email: pbrachman@paulweiss.com

7 William B. Michael (*pro hac vice*)
8 Crystal L. Parker (*pro hac vice*)
9 Daniel A. Crane (*pro hac vice*)
10 **PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP**
11 1285 Avenue of the Americas
12 New York, NY 10019-6064
13 Telephone: (212) 373-3000
14 Facsimile: (212) 757-3990
15 Email: wmichael@paulweiss.com
16 Email: cparker@paulweiss.com
17 Email: dcrane@paulweiss.com

13 Joshua Hill Jr. (SBN 250842)
14 **PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP**
15 535 Mission Street, 24th Floor
16 San Francisco, CA 94105
17 Telephone: (628) 432-5100
18 Facsimile: (628) 232-3101
19 Email: jhill@paulweiss.com
20 *Attorneys for Defendant Intuitive Surgical, Inc.*
21 [Additional counsel listed on signature page]

22
23 **UNITED STATES DISTRICT COURT**
24
25 **NORTHERN DISTRICT OF CALIFORNIA**
26
27 **SAN FRANCISCO DIVISION**
28

23 SURGICAL INSTRUMENT SERVICE
24 COMPANY, INC.,
25 *Plaintiff,*
26 v.
27 INTUITIVE SURGICAL, INC.,
28 *Defendant.*

Case No. 3:21-cv-03496-AMO

DEFENDANT'S PROPOSED JURY INSTRUCTIONS
The Honorable Araceli Martínez-Olguín

PRELIMINARY, GENERAL, AND CONCLUDING INSTRUCTIONS

1.3 Duty of Jury (Court Reads Instructions at the Beginning of Trial but Does Not Provide Written Copies)

1.4 Duty of Jury (Court Reads and Provides Written Instructions at End of Case)

1.6 Burden of Proof—Preponderance of the Evidence

1.9 What is Evidence

1.10 What is Not Evidence

1.11 Evidence for Limited Purpose

1.12 Direct and Circumstantial Evidence

1.13 Ruling on Objections

1.14 Credibility of Witnesses

1.15 Conduct of the Jury

1.16 Publicity During Trial

1.17 No Transcript Available to Jury

1.18 Taking Notes

1.19 Questions to Witnesses by Jurors During Trial (Option 1)

1.20 Bench Conferences and Recesses

1.21 Outline of Trial

2.0 Cautionary Instructions

2.2 Stipulations of Fact

2.3 Judicial Notice

2.4 Deposition in Lieu of Live Testimony

2.13 Expert Opinion

2.14 Charts and Summaries Not Received in Evidence

2.15 Charts and Summaries Received in Evidence

2.16 Evidence in Electronic Format

- 1 3.1 Duty to Deliberate
- 2 3.2 Consideration of Evidence—Conduct of the Jury
- 3 3.3 Communication with Court
- 4 3.4 Readback or Playback
- 5 3.5 Return of Verdict
- 6 3.9 Post-Discharge Instruction
- 7
- 8
- 9
- 10
- 11
- 12
- 13
- 14
- 15
- 16
- 17
- 18
- 19
- 20
- 21
- 22
- 23
- 24
- 25
- 26
- 27
- 28

1 Instruction No. 1 Re Overview of Claims and Defenses¹

2 To help you follow the evidence, I will give you a brief summary of the positions
3 of the parties:

4 The plaintiff in this case is a company called Surgical Instrument Service
5 Company (or “SIS”), based in Glendale Heights, Illinois. The defendant is a company called
6 Intuitive Surgical, based in Sunnyvale, California.

7 Intuitive invented a device called “da Vinci” which is used by surgeons around
8 the world. The da Vinci allows a surgeon sitting at a console to operate on patients by
9 controlling surgical instruments called EndoWrists, also invented by Intuitive. EndoWrists are
10 attached to mechanical arms suspended above the patient, and inserted into the patient’s body
11 through small incisions. As controlled by a surgeon, EndoWrists can perform movements such
12 as cutting, grasping, suturing, etc., allowing surgery to be done in a minimally invasive manner.
13 EndoWrists include fine wire cables that thread through a complex pulley system, allowing the
14 surgeon to move the surgical instruments easily inside the patient’s body to desired angles with
15 great precision, mimicking and even exceeding the range of motion of the human wrist.
16 EndoWrists are designed to be replaced after a specified number of uses, The Food and Drug
17 Administration (FDA) has granted clearance to Intuitive to market and sell the da Vinci and
18 EndoWrist instruments as safe and effective.

19 SIS acted as a distributor for a third-party that sought to modify EndoWrists for
20 the purpose of permitting them to be reused for more than the number of uses specified by
21 Intuitive. SIS alleges that Intuitive’s contracts with its customers prevented customers from
22 purchasing the modified EndoWrist instruments distributed by SIS, and that Intuitive enforced
23 those contractual restrictions by sending cease and desist letters to customers who used modified
24 EndoWrists distributed by SIS. SIS alleges that Intuitive is able to force customers to accept
25 these contractual restrictions because it is a monopolist in what SIS contends is a market for
26

27
28 ¹ MANUAL OF MODEL CIVIL JURY INSTRUCTIONS FOR THE DISTRICT COURTS OF THE NINTH
CIRCUIT § 1.5 (9th Cir. Jury Instructions Comm. 2017 ed.); Complaint (Dkt. 1) ¶¶ 112, 115, 118,
121; Answer (Dkt. 75) p. 39, Counterclaims ¶¶ 85, 93, 99, 102, 106.

1 soft-tissue surgical robots. SIS claims that Intuitive uses its alleged monopoly power to
2 contractually condition the sale and servicing of da Vinci surgical robots on customers'
3 agreement not to purchase EndoWrist instruments that have been modified by a third-party. SIS
4 claims that Intuitive's contracts have allowed Intuitive to monopolize an alleged market for the
5 repair and replacement of EndoWrist instruments.

6 Intuitive denies these claims. Intuitive asserts that customers choose its da Vinci
7 surgical systems over other competing alternatives because Intuitive offers a superior
8 combination of product quality, service and price. Intuitive contends that its customers are
9 highly sophisticated buyers who understand the contract terms and costs associated with da Vinci
10 systems, including EndoWrists, understand that EndoWrists are designed for a limited number of
11 uses, and knowingly and expressly agree not to use EndoWrists that have been modified by any
12 unauthorized third party when they make the choice to buy or lease a da Vinci system. Intuitive
13 asserts that the contractual provisions that SIS challenges were put in place for legitimate and
14 procompetitive reasons, at a time when Intuitive had no significant sales or share of any market.
15 Those reasons include protecting patient safety, ensuring product quality, promoting innovation,
16 and protecting Intuitive's reputation and brand. Intuitive contends that its contracts have not
17 harmed competition or excluded competitors. Intuitive maintains that its contracts restrict only
18 the use of unauthorized third-party products and services, and that SIS chose not to seek
19 authorization for its products and services. Intuitive disputes that it has the power to force
20 customers to accept its contractual terms. Intuitive contends that the da Vinci surgical system
21 competes against other products and methods of performing surgery, and that customers can
22 elect to use those alternative products and surgical methods if they do not wish to accept
23 Intuitive's products, prices, or contract terms.

24 Intuitive also asserts counterclaims against SIS arising out of SIS's marketing,
25 advertising and related activities. *First*, Intuitive alleges that in its marketing materials and
26 communications, SIS made false and misleading statements and engaged in unfair competition.
27 *Second*, Intuitive alleges that SIS engaged in deceptive and fraudulent conduct with the intent to
28 confuse and deceive the public into using its service and purchasing modified EndoWrists.

1 *Third*, Intuitive alleges that SIS was aware of Intuitive’s contractual relationships with its
2 customers that contain limitations concerning the modification or alteration of Intuitive
3 EndoWrists by unauthorized third-parties, and that SIS undertook intentional acts to disrupt
4 and/or induce Intuitive customers to breach those contractual relationships. SIS denies these
5 counterclaims.

I. INTRODUCTORY ANTITRUST INSTRUCTIONS

Instruction No. 2 Re Purpose of Antitrust Laws²

The purpose of the Sherman Act is to preserve free and unfettered competition in the marketplace. The Sherman Act rests on the central premise that competition produces the best allocation of our economic resources, the lowest prices, the highest quality, and the greatest material progress.

The Sherman Act was enacted for the protection of competition, not competitors.³ SIS must therefore establish that Intuitive’s acts caused injury not only to SIS itself but to competition as a whole in the alleged relevant market.

² Model Jury Instructions in Civil Antitrust Cases, Chapter 1 – Sherman Act—General, Instruction 1: Purpose (Am. Bar Ass’n Antitrust L. Section 2016).

³ *Leegin Creative Leather Prods. v. PSKS, Inc.*, 551 U.S. 877, 906 (2007) (“The purpose of the antitrust laws . . . is ‘the protection of competition, not competitors.’” (citation omitted)); *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977) (“The antitrust laws, however, were enacted for ‘the protection of competition not competitors.’” (citations omitted)).

1 Instruction No. 3 Re Communications with FDA⁴

2 You have heard evidence that Intuitive had certain communications with the FDA
3 regarding the actions of third parties with respect to Intuitive's products. The Constitution
4 ensures the right of everyone, whether acting alone or with others, to petition or appeal to
5 government for political action, recognizing that when people do so they will naturally seek
6 political action that favors them and also may be unfavorable to others. The appeal to
7 government may be direct, such as a discussion or meeting with a government official or agency,
8 or it may be indirect, such as a publicity or advertising campaign.

9 The law provides that the right to petition government for political action is an
10 important right, and the genuine exercise of that right does not violate the antitrust laws. Efforts
11 genuinely intended to influence public officials to take official action do not violate the antitrust
12 laws, even if the purpose and effect of those efforts is to obtain official action that eliminates or
13 reduces competition.

14 There is no claim in this case that Intuitive's petitioning of the FDA was
15 unlawful, or that it was not a genuine attempt to influence public officials to take official action.
16 Accordingly, you must not consider Intuitive's communications with the FDA as unlawful or
17 anticompetitive conduct either on their own or in combination with other acts.

18
19
20
21
22
23
24
25
26
27
28

⁴ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 7 – Miscellaneous A. Certain
Defenses and Exemptions, Instruction 3: Noerr-Pennington—Lobbying (AM. BAR ASS'N
ANTITRUST L. SECTION 2016).

1 Instruction No. 4 Re Right to Repair⁵

2 You may have heard about so-called “right to repair” laws in California or
3 elsewhere. There is no “right to repair” medical devices, and such laws have no application in
4 this case.

5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

⁵ See Cal. Pub. Res. Code § 42488; Minn. Stat. § 325E.72; N.Y. Gen. Bus. Law § 399-nn.

1 Instruction No. 5 Re Unilateral Refusal to Deal

2 Antitrust law imposes no obligation on a defendant to help its competitors.⁶ You
3 should therefore not base any finding of an antitrust violation on the fact that Intuitive did not
4 cooperate with SIS to facilitate the sale of modified EndoWrists.⁷

5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26 ⁶ See *FTC v. Qualcomm, Inc.*, 969 F.3d 974, 993–94 (9th Cir. 2020) (citing, *inter alia*, *Pac. Bell*
27 *Tel. Co. v. Linkline Commc'ns, Inc.*, 555 U.S. 438, 457, (2009); *Verizon Commc'ns Inc. v. Law*
28 *Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 408 (2004)).

⁷ Jury Instructions at 26, *AngioDynamics, Inc. v. C.R. Bard, Inc.*, No. 1:17-cv-00598 (N.D.N.Y. Oct. 6, 2022), ECF No. 472.

1 Instruction No. 6 Re Relevant Product Markets⁸

2 For each of SIS's antitrust claims, SIS must prove by a preponderance of the
3 evidence that the relevant markets it alleges are valid antitrust markets.

4 Defining the relevant market is essential because you will be required to make a
5 judgment about whether Intuitive has market power or monopoly power in a properly defined
6 economic market.⁹ To make this judgment, you must be able to determine what, if any,
7 economic forces restrain Intuitive's freedom to set prices for or to restrict the production level of
8 the products or services in question.

9 The most likely and most important restraining force will be actual and potential
10 competition from other firms and their products. This includes all firms and products that act or
11 likely could act as restraints on Intuitive's power to set prices as it pleases because customers
12 could switch to them if Intuitive sets its own prices too high. All the firms and products that
13 exert such restraining force are within what is called the relevant market.

14 There are two aspects you must consider in determining whether SIS has met its
15 burden to prove the relevant market by a preponderance of the evidence. The first is the relevant
16 product market. The second is the relevant geographic market.

17 The basic idea of a relevant product market is that the products within it are
18 reasonable substitutes for each other from the buyer's point of view; that is, the products
19 compete with each other. In other words, the relevant product market includes the products that
20 a consumer believes are reasonably interchangeable or reasonable substitutes for each other.
21 This is a practical test with reference to the actual behavior of buyers and marketing efforts of
22 sellers. Products need not be identical or precisely interchangeable as long as they are
23

24 ⁸ Model Jury Instructions in Civil Antitrust Cases, Chapter 3 – Section 2 of the Sherman Act—
25 Monopolization—General, Instruction 3: Relevant Market—General (Am. Bar Ass'n Antitrust L.
26 Section 2016); Model Jury Instructions in Civil Antitrust Cases, Chapter 3 – Section 2 of the
27 Sherman Act—Monopolization—General, Instruction 4: Relevant Product Market (Am. Bar
28 Ass'n Antitrust L. Section 2016).

⁹ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 3 – Section 2 of the Sherman
Act—Monopolization—General, Instruction 3: Relevant Market—General (AM. BAR ASS'N
ANTITRUST L. SECTION 2016) (modified to add "market power," as the Section 1 claims only
require proof of market power, not monopoly power).

1 reasonable substitutes. Thus, for example, if consumers seeking to cover leftover food for
2 storage considered certain types of flexible wrapping material—such as aluminum foil,
3 cellophane, or even plastic containers—to be reasonable alternatives, then all those products may
4 be in the same relevant product market.

5 To determine whether products or services are reasonable substitutes for each
6 other, you must consider whether a small but significant and non-transitory increase in the price
7 of one product would result in enough customers switching from that product to another product
8 such that the price increase would not be profitable. In other words, will customers accept the
9 price increase or will so many switch to alternative products or services that the price increase
10 will be withdrawn? Generally speaking, a small but significant and non-transitory increase in
11 price is approximately a 5 percent increase in price not due to cost factors, but you may conclude
12 in this case that some other percentage is more applicable to the products at issue. If you find
13 that customers would switch and that the price increase would not be profitable, then you must
14 conclude that the products are in the same product market. If, on the other hand, you find that
15 customers would not switch, then you must conclude that the products are not in the same
16 product market.

17 In evaluating whether various products or services are reasonably interchangeable
18 or reasonable substitutes for each other under the price increase test I have just given you, you
19 may also consider:

- 20 • customers' views on whether the products are interchangeable;
- 21 • the relationship between the price of one product and sales of another;
- 22 • the presence or absence of specialized vendors;
- 23 • the perceptions of either industry or the public as to whether the products
24 are in separate markets;
- 25 • the views of SIS and Intuitive regarding who their respective competitors
26 are; and
- 27 • the existence or absence of different customer groups or distribution
28 channels.

1 In this case, SIS alleges there are two separate relevant product markets: (1) an
 2 alleged market for surgical robots used in minimally invasive soft tissue (or “MIST”) surgery;
 3 and (2) an alleged aftermarket for EndoWrist repair and replacement.

4 Intuitive disputes SIS’s definition of the alleged relevant markets.

5 First, Intuitive contends that the relevant product market in which Intuitive’s da
 6 Vinci system competes includes all types (or “modalities”) of surgery available to doctors to treat
 7 the conditions that can be treated by the da Vinci. In particular, Intuitive contends that its da
 8 Vinci system competes not just with other MIST surgical robots, but with laparoscopic surgery
 9 and open surgery as well.

10 Second, Intuitive contends that the alleged aftermarket for EndoWrist repair and
 11 replacement is an improperly defined single-brand aftermarket—that is, a market that is
 12 improperly limited to Intuitive’s own brand of products.

13 To establish a valid single-brand aftermarket, SIS must prove each of the
 14 following four factors by a preponderance of the evidence:

15 (1) the challenged aftermarket restrictions (which, here, are the alleged
 16 restrictions that Intuitive places in its contracts on the use with the da Vinci system of
 17 unauthorized instruments or instruments that have been modified by unauthorized third parties)
 18 are not generally known when hospitals make their “foremarket” purchase of the da Vinci
 19 system;

20 (2) significant information costs prevent hospitals from forecasting life-cycle
 21 pricing accurately at the time they purchase their da Vinci surgical systems;

22 (3) significant monetary or non-monetary switching costs exist; and

23 (4) general market-definition principles regarding cross-elasticity of demand, like
 24 those on which I have instructed you, do not undermine SIS’s proposed single-brand market.¹⁰

25 As I said earlier, the second aspect of the relevant market is the geographic scope
 26 of the market. SIS and Intuitive agree that the relevant geographic market is the United States.

27
 28 ¹⁰ *Epic Games, Inc. v. Apple, Inc.*, 67 F.4th 946, 976–77 (9th Cir. 2023); *Newcal Indus. Inc. v. Ikon Office Solutions*, 513 F.3d 1038, 1046–51 (9th Cir. 2008).

1 If you find that SIS has failed to prove by a preponderance of the evidence either
2 of the two relevant markets it alleges based on the instructions I have given you, then you must
3 find for Intuitive on all of SIS's claims.¹¹ If you find that SIS has proven the relevant markets it
4 alleges, then you should continue to evaluate the remainder of SIS's claims.¹²

25 _____
26 ¹¹ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 3 – Section 2 of the Sherman
27 Act—Monopolization—General, Instruction 4: Relevant Product Market (AM. BAR ASS'N
28 ANTITRUST L. SECTION 2016) (modified to apply to all claims).

¹² MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 3 – Section 2 of the Sherman
Act—Monopolization—General, Instruction 4: Relevant Product Market (AM. BAR ASS'N
ANTITRUST L. SECTION 2016) (modified to apply to all claims).

Instruction No. 7 Re Relevant Product Markets – Supply Substitutability¹³

In deciding whether SIS has proven a relevant product market, you may also consider what the law refers to as “the cross-elasticity of supply” or, in other words, the extent to which the producers of one product would be willing to shift their resources, such as intellectual property, manufacturing facilities, or personnel to producing another product in response to an increase in the price of the other product. Such producers, to the extent that they exist, can increase supply and, therefore, drive prices back to competitive levels, defeating any effort by a would-be monopolist to charge significantly higher prices.

Take two shoe manufacturers, for example. The first manufacturer produces shoes for women, while the second manufacturer produces shoes for men. Generally speaking, men’s and women’s shoes are not reasonably interchangeable and, therefore, might be thought of as being in a separate product markets. However, it is possible that the men’s shoe manufacturer could quickly shift its resources to start producing women’s shoes if the women’s shoe manufacturer raised its prices significantly and vice versa. Although women would not buy men’s shoes, nor would men buy women’s shoes, the ability of each manufacturer to alter its production could prevent the other manufacturer from raising prices significantly. Thus, in this example, men’s and women’s shoes would be included in the same market.

If, in determining the products in the relevant product market you find that there are manufacturers that have the ability to alter their production to manufacture products that can be reasonably substituted with Intuitive’s—even though they do not presently compete with Intuitive—you may consider whether the existence of these potential alternative suppliers constrain the prices that Intuitive charges for its products.

¹³ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 3 – Section 2 of the Sherman Act—Monopolization—General, Instruction 5: Relevant Product Market—Supply Substitutability (AM. BAR ASS’N ANTITRUST L. SECTION 2016) (modified to reflect the particular products and services at issue).

II. ANTITRUST - SECTION 1 OF THE SHERMAN ACT

A. Sherman Act Section 1 Claims Generally

Instruction No. 8 Re Sherman Act Section 1¹⁴

SIS brings two claims against Intuitive under Section 1 of the Sherman Act. Section 1 prohibits contracts, combinations and conspiracies that unreasonably restrain trade. The first claim is for “tying,” and the second claim is for “exclusive dealing.”¹⁵

Section 1 of the Sherman Act prohibits contracts, combinations and conspiracies that unreasonably restrain trade.

To establish a violation of Section 1 of the Sherman Act, SIS must prove the following:

1. The existence of a contract, combination, or conspiracy between or among at least two separate entities;
2. That the contract, combination, or conspiracy unreasonably restrains trade; and
3. That the restraint caused plaintiff to suffer an injury to its business or property.

Both of SIS’s claims under Section 1 of the Sherman Act are based on features of Intuitive’s contracts with purchasers of da Vinci surgical robots. While Intuitive does not contest the existence of such contracts, Intuitive denies that such contracts unreasonably restrained trade.

¹⁴ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 1 – Sherman Act—General, Instruction 2: Sherman Act Section 1 (AM. BAR ASS’N ANTITRUST L. SECTION 2016) (modified to remove element that the challenged restraint must “affect[] interstate or foreign commerce,” which is not contested); *see also* 15 U.S.C. § 1.

¹⁵ Complaint (Dkt. 1) ¶¶ 112, 115.

Instruction No. 9 Re Rule of Reason Overview¹⁶

Under Section 1 of the Sherman Act, a restraint of trade is illegal only if it is found to be unreasonable. You must determine, therefore, whether the restraints challenged by SIS here—namely, the alleged restrictions that Intuitive places in its contracts on the use with the da Vinci system of unauthorized instruments or instruments that have been modified by unauthorized third parties—are unreasonable. In making this determination, you must first determine whether SIS has proven that the challenged restraint has resulted in a substantial harm to competition in a relevant product and geographic market. If you find that SIS has proven that the challenged restraint results in a substantial harm to competition in a relevant market, then you must consider whether Intuitive has shown that the restraint produces countervailing competitive benefits.

¹⁶ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 1 – Sherman Act—General, Instruction 3A: Rule of Reason – Overview (AM. BAR ASS’N ANTITRUST L. SECTION 2016) (modified to remove final instruction that “The challenged restraint is illegal under Section 1 of the Sherman Act only if you find that the competitive harm substantially outweighs the competitive benefit,” as this balancing is not an element supported by Supreme Court precedent. *See, e.g., Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2284 (2018) (“To determine whether a restraint violates the rule of reason, the parties agree that a three-step, burden-shifting framework applies. Under this framework, the plaintiff has the initial burden to prove that the challenged restraint has a substantial anticompetitive effect that harms consumers in the relevant market. . . . If the plaintiff carries its burden, then the burden shifts to the defendant to show a procompetitive rationale for the restraint. . . . If the defendant makes this showing, then the burden shifts back to the plaintiff to demonstrate that the procompetitive efficiencies could be reasonably achieved through less anticompetitive means.” (citations omitted)); *Nat’l Collegiate Athletic Ass’n v. Alston*, 141 S. Ct. 2141, 2160, 2162 (2021) (endorsing the *American Express* burden-shifting framework); *FTC v. Qualcomm Inc.*, 969 F.3d 974, 99192 (9th Cir. 2020) (adopting the *American Express* burden-shifting framework)) The Court in this case likewise adopted the three-step burden shifting framework of *American Express* in its opinion regarding the parties’ cross-motions for summary judgment, and nowhere mentioned a fourth step requiring a balancing analysis. *See* Dkt. 204 at 17.).

1 Instruction No. 10 Re Rule of Reason Proof of Competitive Harm¹⁷

2 As I mentioned, to prove that the challenged restraints are unreasonable, SIS first
3 must demonstrate that the restraints have resulted in a substantial harm to competition. Although
4 it may be relevant to the inquiry, harm that occurs merely to the individual business of SIS is not
5 sufficient, by itself, to demonstrate harm to competition generally. Harm to competition is to be
6 distinguished from harm to a single competitor or group of competitors, which does not
7 necessarily constitute harm to competition.

8 Furthermore, SIS must show that the harm to competition occurred in an
9 identified market, known as a relevant market. There are two aspects to a relevant market. The
10 first aspect is known as the relevant product market. The second aspect is known as the relevant
11 geographic market. It is SIS's burden to prove the existence of a relevant market. I instructed
12 you earlier on how to make this assessment. In this case, SIS alleges competitive harm only in
13 one market: the alleged aftermarket for EndoWrist replacement or repair; SIS does not allege
14 any competitive harm in the alleged market for surgical robots used in MIST surgery.

15 If you find that SIS has proven the existence of a relevant market, then you must
16 determine whether SIS also have proven that the challenged restraints have a substantial harmful
17 effect on competition in that market. A harmful effect on competition, or competitive harm,
18 refers to a reduction in competition that results in the loss of some of the benefits of competition,
19 such as lower prices, increased output, or higher product quality. It is not enough that the
20 conduct at issue has the effect of reducing consumers' choices or increasing prices to
21 consumers.¹⁸ If the challenged conduct has not resulted in higher prices, decreased output, lower
22 quality, or the loss of some other competitive benefit, then there has been no competitive harm,
23 and you should find that the challenged conduct was not unreasonable.

24
25
26 ¹⁷ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 1 – Sherman Act—General,
27 Instruction 3B: Rule of Reason – Proof of Competitive Harm (AM. BAR ASS'N ANTITRUST L.
SECTION 2016).

28 ¹⁸ Dkt. 204 at 17 (quoting *FTC v. Qualcomm, Inc.*, 969 F.3d 974, 993–94 (9th Cir. 2020)
(quoting *Brantley v. NBC Universal, Inc.*, 675 F.3d 1192, 1202 (9th Cir. 2012))).

1 In determining whether the challenged restraint has produced competitive harm,
2 you may look at the following factors:

- 3 • the effect of the restraint on prices, output, product quality, and service;
- 4 • the purpose and nature of the restraint;
- 5 • the nature and structure of the relevant market;
- 6 • the number of competitors in the relevant market and the level of
- 7 competition among them, both before and after the restraint was imposed;
- 8 and
- 9 • whether the defendant possesses market power.

10 The last factor mentioned, market power, has been defined as an ability to
11 profitably raise prices, for a sustained period of time, above those that would be charged in a
12 competitive market. A firm that possesses market power generally can charge higher prices for
13 the same goods or services than a firm in the same market that does not possess market power.
14 The ability to charge higher prices for better products or services, however, is not market power.
15 An important factor in determining whether Intuitive possesses market power is Intuitive's
16 market share, that is, its percentage of the products or services sold in the relevant market by all
17 competitors. Other factors that you may consider in determining whether Intuitive has market
18 power include market share trends, the existence of barriers to entry (that is, how difficult is it
19 for other producers to enter the market and begin competing with defendant for sales), the entry
20 and exit by other companies, and the number and size of actual competitors or potential
21 competitors. If Intuitive does not possess a substantial market share, it is less likely that Intuitive
22 possesses market power. If Intuitive does not possess market power, it is less likely that the
23 challenged restraints have resulted in a substantial harmful effect on competition in the market.

24
25
26
27
28

1 Instruction No. 11 Re Rule of Reason Evidence of Competitive Benefits¹⁹

2 If you find that SIS has proven that the challenged restraints resulted in
3 substantial harm to competition in a relevant market, then you next must determine whether next
4 must determine whether the restraint also benefits competition in other ways. If you find that the
5 challenged restraints do result in competitive benefits, then you also must consider whether the
6 challenged restraints were reasonably necessary to achieve the benefits. If SIS proves that the
7 same benefits could have been readily achieved by other, reasonably available alternative means
8 that create substantially less harm to competition, then they cannot be used to justify the
9 challenged restraints.

10 Antitrust law does not require businesses like Intuitive to use the least restrictive
11 means of achieving a legitimate business purpose. Any alternative to the challenged conduct
12 presented by SIS must be a substantially—not marginally—less restrictive means for achieving
13 the same procompetitive rationales. A procompetitive rationale is a nonpretextual claim that a
14 defendant’s conduct is indeed a form of competition on the merits because it involves, for
15 example, greater efficiency or enhanced consumer appeal.²⁰ To qualify as substantially less
16 restrictive, an alternative means must be virtually as effective in serving the Intuitive’s
17 procompetitive purposes without significantly increased cost.²¹

21 _____
22 ¹⁹ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 1 – Sherman Act—General,
23 Instruction 3C: Rule of Reason – Evidence of Competitive Benefits (AM. BAR ASS’N ANTITRUST
24 L. SECTION 2016).

25 ²⁰ Dkt. 204 at 17 (quoting *FTC v. Qualcomm Inc.*, 969 F.3d 974, 991 (9th Cir. 2020)).

26 ²¹ *Epic Games, Inc. v. Apple, Inc.*, 67 F.4th 946, 990 (9th Cir. 2023) (“When evaluating proposed
27 alternative means, courts must give wide berth to defendants’ business judgments and must resist
28 the temptation to require that enterprises employ the least restrictive means of achieving their
legitimate business objectives. . . . As such, this circuit’s test—which the Supreme Court
approved in *Alston*—requires a substantially less restrictive alternative.” (quotations omitted)
(citing *Alston*, 141 S. Ct. at 2161, 2163 (2021); *id.* (“To qualify as “substantially less restrictive,”
an alternative means “must be ‘virtually as effective’ in serving the [defendant’s] procompetitive
purposes . . . without significantly increased cost.” (citing *Cnty. of Tuolumne v. Sonora Cmty.*
Hosp., 236 F.3d 1148, 1159 (9th Cir. 2001))).

1 **B. SIS's Tying Claim**

2 Instruction No. 12 Re Definition of Tying Arrangements²²

3 SIS claims that Intuitive engaged in an unlawful tying arrangement. Intuitive
4 denies this claim.

5 A tying arrangement is one in which the seller will sell one product (referred to as
6 the tying product) only on the condition that buyers also purchase a different product (referred to
7 as the tied product) from the seller, or at least agrees that he will not purchase the tied product
8 from any other supplier. In this case, SIS claims that the da Vinci surgical robot is the tying
9 product and EndoWrist repair and replacement is the tied product.

10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27

28 ²² MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 2 – Section 1 of the Sherman
Act—Tying Arrangements, Instruction 1: Definition (AM. BAR ASS'N ANTITRUST L. SECTION
2016).

1 Instruction No. 13 Re Rationale for Prohibition of Tying Arrangements²³

2 Not all tying arrangements are unlawful. The essential characteristic of an invalid
3 tying arrangement is a seller's exploitation of its market power over the tying product (here, the
4 da Vinci surgical robot) to force buyers to purchase a tied product (here, EndoWrist repair or
5 replacement) that buyers might have preferred to purchase elsewhere. However, the law also
6 recognizes that tying arrangements may have legitimate justifications that benefit buyers.²⁴
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26

27 ²³ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 2 – Section 1 of the Sherman
28 Act—Tying Arrangements, Instruction 2: Rationale for Prohibition of Tying Arrangements
(AM. BAR ASS'N ANTITRUST L. SECTION 2016).

²⁴ Ill. Tool Works Inc. v. Independent Ink, Inc., 547 U.S. 28, 35–36 (2006).

1 Instruction No. 14 Re Elements of Unlawful Tying²⁵

2 To prevail on its tying claim, SIS must prove each of the following elements by a
3 preponderance of the evidence:

- 4 1. MIST surgical robots and EndoWrist repair and replacement are separate
5 and distinct products;
- 6 2. Intuitive will sell da Vinci surgical robots only on the condition that the
7 buyer also purchase replacement EndoWrists from Intuitive, or that the
8 buyer not purchase repaired or replacement EndoWrists from any other
9 supplier;
- 10 3. Intuitive has sufficient market power with respect to MIST surgical robots
11 to enable it to restrain competition as to EndoWrist repair and
12 replacement;
- 13 4. the alleged tying arrangement has foreclosed a substantial volume of
14 commerce as to EndoWrist repair and replacement;
- 15 5. the alleged tying arrangement has unreasonably restrained trade in that it
16 had a substantial adverse effect on competition as to EndoWrist repair and
17 replacement; and
- 18 6. SIS was injured in its business or property because of the alleged tying
19 arrangement.²⁶

20 If you find that the evidence is sufficient to prove all six of these elements, then
21 you must find for SIS and against Intuitive on SIS's tying claim. If you find that the evidence is
22

23 _____
24 ²⁵ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 2 – Section 1 of the Sherman
25 Act—Tying Arrangements, Instruction 4: Elements – Unlawful Tying Under Rule of Reason
(AM. BAR ASS'N ANTITRUST L. SECTION 2016).

26 ²⁶ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 2 – Section 1 of the Sherman
27 Act—Tying Arrangements, Instruction 4: Elements – Unlawful Tying Under Rule of Reason
28 (AM. BAR ASS'N ANTITRUST L. SECTION 2016) (modified to remove elements that the conduct
must have “occurred in or affected interstate commerce” and that the defendant “has a financial
interest” in the tied product, which are not contested); *see also Aerotec Int'l, Inc. v. Honeywell
Int'l, Inc.*, 836 F.3d 1171, 1178–1180 (9th Cir. 2016); *Epic Games v. Apple, Inc.*, 67 F.4th 946,
995 (9th Cir. 2023).

1 insufficient to prove any one of these elements, then you must find for Intuitive and against SIS
2 on SIS's tying claim.
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

1 Instruction No. 15 Re Presence of Two Products²⁷

2 The first element of its tying claim that SIS must prove by a preponderance of the
3 evidence is that the da Vinci surgical robot is a separate and distinct product from the repair and
4 replacement of EndoWrists.

5 To determine whether the da Vinci surgical robot and EndoWrist repair and
6 replacement are separate and distinct products, you should consider whether there would be
7 demand for each of them if they were offered separately. If enough customers would want to
8 purchase the da Vinci surgical robot alone and EndoWrist repair or replacement alone, then they
9 are separate products. On the other hand, if there is very little demand for one of the products by
10 itself, that is, without purchasing the other product at the same time, then the da Vinci surgical
11 robot and EndoWrist repair and replacement are not two separate products for the purposes of
12 the tying claim, even if they are sometimes sold separately.

13 Products may be separate products even if one of them is useless without the
14 other. The relevant issue is whether there is sufficient demand from customers to induce sellers
15 to provide them separately, even if the customer needs to obtain both products from one or more
16 suppliers.

17 If you determine that MIST surgical robots are not a separate product from
18 EndoWrist repair and replacement, then you must find for Intuitive on SIS's tying claim. If you
19 determine that MIST surgical robots are a separate product from EndoWrist repair and
20 replacement, then you must go on to assess the other elements of SIS's tying claim.

21
22
23
24
25
26
27
28

²⁷ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 2 – Section 1 of the Sherman
Act—Tying Arrangements, Instruction 5: Presence of Two Products (AM. BAR ASS'N
ANTITRUST L. SECTION 2016).

1 Instruction No. 16 Re Proof of Coercion²⁸

2 The second element of its tying claim that SIS must prove by a preponderance of
3 the evidence is that Intuitive will sell da Vinci surgical robots only on the condition that the
4 buyer also purchase replacement EndoWrists from Intuitive, or that the buyer not purchase
5 repaired or replacement EndoWrists from any other supplier.

6 You may find that a tying arrangement exists between da Vinci surgical robots
7 and EndoWrist repair and replacement if SIS proves that Intuitive either refused to sell da Vinci
8 surgical robots unless purchasers also agreed not to buy EndoWrist repair or replacement from
9 another supplier, or effectively coerced purchasers into buying replacement EndoWrists in
10 addition to da Vinci surgical robots from Intuitive. To prove coercion, SIS must prove by a
11 preponderance of the evidence that Intuitive exploited its control over da Vinci surgical robots to
12 force buyers into the purchase of replacement EndoWrists, which the buyers either did not want
13 at all, or might have preferred to purchase elsewhere on different terms, and that any appearance
14 of choice was illusory. Mere sales pressure or persuasion is not coercion.

15 If Intuitive has made the purchase of da Vinci surgical robots and replacement
16 EndoWrists together the only viable economic option, you may find that Intuitive has effectively
17 tied da Vinci surgical robots to EndoWrist repair and replacement. However, there is no coercion
18 if da Vinci surgical robots and EndoWrist repair and replacement are offered separately for sale
19 and separate purchase is economically feasible.

20 If you determine that SIS has not proven by a preponderance of the evidence that
21 Intuitive effectively coerced buyers of da Vinci surgical robots to purchase EndoWrist repair and
22 replacement solely from Intuitive, then you must find for Intuitive on SIS's tying claim. If you
23 determine that SIS has proven such coercion by a preponderance of the evidence, then you must
24 go on to assess the other elements of SIS's tying claim.

25
26
27
28 ²⁸ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 2 – Section 1 of the Sherman
Act—Tying Arrangements, Instruction 7: Proof of Conditioning (AM. BAR ASS'N ANTITRUST L.
SECTION 2016).

1 Instruction No. 17 Re Restrictions on Unauthorized Third-Party Products and Services Are Not
 2 Coercion

3 SIS challenges provisions of Intuitive’s contracts with customers that restrict the
 4 use of unauthorized third-party products and services in connection with the da Vinci system as
 5 an unlawful tie. If the seller of a product or service contractually requires its customers to buy
 6 another product or service either from the seller or from third parties that seller authorizes, such a
 7 contractual provision is not a tying arrangement unless third parties cannot realistically obtain
 8 such authorization from the seller. SIS bears the burden of demonstrating that third parties could
 9 not realistically obtain authorization from Intuitive and hence that third-party authorization was
 10 illusory. If you find that SIS fails to meet this burden, then you must find that SIS has failed to
 11 meet its burden of proving coercion and, accordingly, you must find in favor of Intuitive on
 12 SIS’s tying claim.²⁹

13
14
15
16
17
18
19
20
21 ²⁹ *Mozart v. Mercedes-Benz*, 593 F. Supp. 1506, 1517 (N.D. Cal. 1984) (citing *United States v.*
 22 *Mercedes-Benz of N. Am., Inc.*, 517 F. Supp. 1369, 1383–84 (N.D. Cal. 1981)) (where the
 23 defendant asks customers only to work with “authorized” third parties, there is no forcing or
 24 coercion unless the option for third parties to become authorized is “illusory”); *see also Ford*
 25 *Motor v. GMB Universal Joints*, 1988 WL 82826, at *3 (9th Cir. 1988) (“[a]n approval
 26 mechanism must not be illusory”) (unpublished disposition) (citing *Mozart*, 593 F. Supp. at
 27 1517); *Photovest v. Fotomat*, 606 F.2d 704, 722 (7th Cir. 1979) (“Given the contractual
 28 language, which at least provides for the possibility of purchasing processing from non-Fotomat
 sources, we are reluctant to find a tying arrangement without some evidence that Fotomat
 applied the contract language so restrictively as to constitute a de facto tying clause. The
 presence of the illegal condition may be inferred from an extrinsic course of conduct
 supplementing the written contract, but in the present case Photovest has failed to provide
 evidence of any conduct from which to infer the tie.” (quotation marks and internal citation
 omitted)).

Instruction No. 18 Re Voiding a Warranty Is Not Coercion

You have heard testimony that Intuitive’s contracts with its hospital customers provide that Intuitive’s warranties on its products are voided if the customer uses an unauthorized third-party product or service in connection with the da Vinci system. Contractual provisions such as these—which existed at the time the customer chose to purchase the product, and which provide that the manufacturer may not honor a warranty if the customer uses unauthorized service providers or unauthorized parts or accessories with the equipment—are not considered to be so coercive to create a tying arrangement.³⁰ Thus, you may not consider as evidence of coercion any provision in Intuitive’s contracts that would void a warranty if the customer uses an unauthorized third-party product or service.

³⁰ *Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 870 (Fed. Cir. 1997) (“Voiding a warranty on a product already sold, while possibly a breach of warranty, cannot be a tying arrangement because the purchaser is not deciding whether to buy a product.”); *Marts v. Xerox, Inc.*, 77 F.3d 1109, (8th Cir. 1996) (“Although the warranty does condition its continuation on the use of Xerox cartridges, a warranty is only one way of receiving service for a new Xerox copier. . . . An owner of a new Xerox copier could forego the benefits of the warranty, buy service from Xerox or an independent provider, and purchase cartridges from the vendor of its choice.”); *General Motors v. Gibson Chem. & Oil Co.*, 786 F.2d 105, 110 (2d Cir. 1986) (“[T]he sale of a GM automobile is not conditioned on the purchase of Dexron II. GM simply recommends use of the fluid in its automatic transmissions and cautions that damage to transmissions caused by the use of other fluids may not be covered by the automobile warranty. This manufacturer’s recommendation is not the degree of coercion necessary to a tying arrangement.”); *DSM Desotech Inc. v. 3D Sys. Corp.*, 2009 WL 174989 (N.D. Ill. Jan. 26, 2009) (allegations of enforcing a warranty provision “do not amount to a tie-in” because customers had already purchased their machines “at the time the alleged tie-in was executed”); *Fido’s Fences v. Canine Fence Company*, 672 F. Supp. 2d 303, 312 (E.D.N.Y. 2009) (holding that “it is well settled that warranties that are not sold as a separate product do not result in consumer coercion if the warranty sets forth requirements”).

Instruction No. 20 Re Existence of Market Power With Respect to the Tying Product³¹

The third element of its tying claim that SIS must prove by a preponderance of the evidence is that Intuitive has sufficient market power in the alleged market for MIST surgical robots to enable Intuitive to restrain competition as to the alleged aftermarket for EndoWrist repair and replacement.

You may find that Intuitive has market power with respect to MIST surgical robots if, by reason of some advantage, Intuitive has the power to raise its prices for MIST surgical robots without losing an appreciable amount of its business, or otherwise has the power to force a purchaser of MIST surgical robots to do something that the purchaser would not do in a more competitive market. The ability to charge higher prices for better products or services, however, is not market power.³²

SIS may prove power over price with respect to MIST surgical robots by establishing that the price of the tied package is higher than the price of components sold in competitive markets.

In the alternative, you may determine whether Intuitive has market power with respect to MIST surgical robots by considering whether Intuitive has a high share of that market for MIST surgical robots such that purchasers do not have alternative sources of minimally invasive surgical robots or a reasonably interchangeable substitute readily available. If Intuitive's market share of the market for minimally invasive surgical robots is below 30 percent, Intuitive does not have market power. But if Intuitive's market share of the market for MIST surgical robots is above 30 percent, you may consider that in determining whether Intuitive has market power. Whether a high market share is an indicator of Intuitive's power to raise prices without loss of appreciable business is a function of numerous market conditions, including the uniqueness of the product, the ability of existing competitors to expand production, and the ease

³¹ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 2 – Section 1 of the Sherman Act—Tying Arrangements, Instruction 8: Existence of Market Power with Respect to the Tying Product (AM. BAR ASS'N ANTITRUST L. SECTION 2016).

³² MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 1 – Sherman Act—General, Instruction 3B: Rule of Reason – Proof of Competitive Harm (AM. BAR ASS'N ANTITRUST L. SECTION 2016).

1 (or difficulty) with which new competitors can enter the market and make a price increase
2 unprofitable. If you find that purchasers of MIST surgical robots do not have readily available
3 alternative sources of supply and are forced as a practical matter to buy MIST surgical robots,
4 you may find that Intuitive has market power. You may also consider in your market power
5 determination the presence of any unique features or costs associated with MIST surgical robots
6 that effectively prevent others from offering a comparable product
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

1 Instruction No. 21 Re Foreclosure of a Substantial Volume of Commerce With Respect to the
 2 Tied Product³³

3 If you determine that da Vinci surgical robots and EndoWrist repair and
 4 replacement are separate products that have been tied to one another, and that Intuitive has
 5 market power for MIST surgical robots, then you must determine whether SIS has proven that
 6 Intuitive has foreclosed a substantial amount of interstate commerce with respect to EndoWrist
 7 repair and replacement.

8 In determining whether Intuitive has foreclosed a substantial amount of commerce
 9 with respect to EndoWrist repair and replacement, you should first consider the total dollar
 10 amount of Intuitive's sales of repaired and replacement EndoWrists achieved by the tying
 11 arrangement in absolute terms.

12 If the dollar amount of Intuitive's sales of repaired and replacement EndoWrists
 13 was substantial, you should next consider whether there has been a substantial adverse effect on
 14 competition with respect to EndoWrist repair and replacement due to the tying arrangement. If
 15 there was not a substantial adverse effect on competition with respect to EndoWrist repair and
 16 replacement due to the tying arrangement, then you must find in favor of Intuitive on the tying
 17 claim.

18 There is no substantial foreclosure if only a small percentage of sales in the
 19 alleged aftermarket for EndoWrist repair and replacement were affected by the tying
 20 arrangement. There also is no substantial foreclosure if you find that purchasers would not have
 21 bought EndoWrist repair or replacement at all in the absence of the tying arrangement.
 22 If you determine that SIS has failed to prove by a preponderance of the evidence that Intuitive
 23 foreclosed a substantial amount of commerce with respect to EndoWrist repair and replacement,
 24 then you must find for Intuitive on SIS's tying claim. If you determine that SIS has proved
 25 foreclosure of a substantial amount of commerce, then you must go on to assess the other elements
 26 of SIS's tying claim.

27 _____
 28 ³³ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 2 Section 1 of the Sherman
 Act—Tying Arrangements, Instruction 9: Foreclosure of a Substantial Volume of Commerce
 with Respect to the Tied Product (AM. BAR ASS'N ANTITRUST L. SECTION 2016).

Instruction No. 24 Re Substantial Harm to Competition³⁴

As I mentioned, to prove that the alleged tie is unreasonable, SIS first must demonstrate that the tie has resulted in a substantial harm to competition. Although it may be relevant to the inquiry, harm that occurs merely to the individual business of SIS is not sufficient, by itself, to demonstrate harm to competition generally. That is, harm to a single competitor or group of competitors does not necessarily mean that there has been harm to competition.

Furthermore, SIS must show that the harm to competition occurred in the alleged aftermarket for EndoWrist repair and replacement. It is SIS's burden to prove the existence of a relevant market. I instructed you earlier on how to make this assessment.

If you find that SIS has proven the existence of a relevant market, then you must determine whether SIS also has proven that the challenged restraints have had a substantial harmful effect on competition in that market. A harmful effect on competition, or competitive harm, refers to a reduction in competition that results in the loss of some of the benefits of competition, such as lower prices, increased output, or higher product quality. It is not enough that the conduct at issue has the effect of reducing consumers' choices or increasing prices to consumers.³⁵ If the challenged conduct has not resulted in higher prices, decreased output, lower quality, or the loss of some other competitive benefit, then there has been no competitive harm, and you should find that the challenged conduct was not unreasonable.

In determining whether the challenged restraints have produced competitive harm, you may look at the following factors:

- the effect of the restraints on prices, output, product quality, and service;
- the purpose and nature of the restraint;
- the nature and structure of the relevant market;

³⁴ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 1 – Sherman Act—General, Instruction 3B: Rule of Reason – Proof of Competitive Harm (AM. BAR ASS'N ANTITRUST L. SECTION 2016).

³⁵ Dkt. 204 at 17 (quoting *FTC v. Qualcomm, Inc.*, 969 F.3d 974, 993–94 (9th Cir. 2020) (quoting *Brantley v. NBC Universal, Inc.*, 675 F.3d 1192, 1202 (9th Cir. 2012))).

- the number of competitors in the relevant market and the level of competition among them, both before and after the restraint was imposed; and
- whether Intuitive possesses market power (a concept on which I have previously instructed you).

If you find that SIS has failed to prove a substantial competitive harm by a preponderance of the evidence, then you must find for Intuitive on SIS's tying claim. If you find that SIS has proved substantial competitive harm, then you must go on to assess the other elements of SIS's tying claim.

1 Instruction No. 25 Re Evidence of Competitive Benefits³⁶

2 If you find that SIS has proven that the challenged restraints resulted in
3 substantial harm to competition in a relevant market, then you next must determine whether
4 Intuitive has proven that the restraints also benefit competition in other ways. If you find that the
5 challenged restraints do result in competitive benefits, then you also must consider whether the
6 restraint was reasonably necessary to achieve the benefits. If SIS proves that the same benefits
7 could have been readily achieved by other, reasonably available alternative means that create
8 substantially less harm to competition, then they cannot be used to justify the restraint.

9 Antitrust law does not require businesses like Intuitive to use the least restrictive
10 means of achieving a legitimate business purpose. Any alternative to the challenged conduct
11 presented by SIS must be a substantially—not marginally—less restrictive means for achieving
12 the same procompetitive rationales. A procompetitive rationale is a nonpretextual claim that a
13 defendant’s conduct is indeed a form of competition on the merits because it involves, for
14 example, greater efficiency or enhanced consumer appeal.³⁷ To qualify as substantially less
15 restrictive, an alternative means must be virtually as effective in serving the Intuitive’s
16 procompetitive purposes without significantly increased cost.³⁸

21 _____
22 ³⁶ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 1 – Sherman Act—General,
23 Instruction 3C: Rule of Reason – Evidence of Competitive Benefits (AM. BAR ASS’N ANTITRUST
24 L. SECTION 2016).

25 ³⁷ Dkt. 204 at 17 (quoting *FTC v. Qualcomm Inc.*, 969 F.3d 974, 991 (9th Cir. 2020)).

26 ³⁸ *Epic Games, Inc. v. Apple, Inc.*, 67 F.4th 946, 990 (9th Cir. 2023) (“When evaluating proposed
27 alternative means, courts must give wide berth to defendants’ business judgments and must resist
28 the temptation to require that enterprises employ the least restrictive means of achieving their
legitimate business objectives. . . . As such, this circuit’s test—which the Supreme Court
approved in *Alston*—requires a substantially less restrictive alternative.” (quotations omitted)
(citing *Alston*, 141 S. Ct. at 2161, 2163 (2021); *id.* (“To qualify as “substantially less restrictive,”
an alternative means “must be ‘virtually as effective’ in serving the [defendant’s] procompetitive
purposes . . . without significantly increased cost.” (citing *Cnty. of Tuolumne v. Sonora Cmty.*
Hosp., 236 F.3d 1148, 1159 (9th Cir. 2001))).

Instruction No. 26 Re Business Justification Defense³⁹

Intuitive contends that the alleged tying arrangement is justified. If you find that SIS has proven all elements of a tying claim, then you should consider whether Intuitive has proven, by a preponderance of the evidence, a business justification for the tying arrangement. Intuitive has the burden of proof on this issue.

Intuitive contends that its contractual restrictions on the unauthorized modification of EndoWrists by third parties are justified by procompetitive patient safety as well as business reasons including, for example, that: Intuitive’s da Vinci system was designed to work with Intuitive’s proprietary EndoWrist instruments; the use of EndoWrist instruments beyond the number of lives specified in their Instructions for Use and cleared by the FDA presents serious risks to health and safety of patients; Intuitive has no way to ensure the safety and effectiveness of unauthorized third-party products and services that have not been cleared by the FDA; by posing risks to patient health and safety, the use of unauthorized third-party products and services with the da Vinci surgical system also poses a risk to Intuitive’s reputation in the marketplace and would expose Intuitive to additional costs and liability that Intuitive’s contracts help to avoid; and allowing unauthorized third parties to modify Intuitive’s EndoWrists would permit such third parties to “free ride” on Intuitive’s goodwill and the substantial investments Intuitive has made in developing and creating the da Vinci surgical system.⁴⁰

In determining whether the tying arrangement is justified, you must decide whether it serves a legitimate business purpose of Intuitive. In making this determination, you

³⁹ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 2 Section 1 of the Sherman Act—Tying Arrangements, Instruction 11: Business Justification Defense (AM. BAR ASS’N ANTITRUST L. SECTION 2016).

⁴⁰ See *Cont’l T. V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 55 n.23 (1977) (recognizing legitimate justifications arising from federal and state laws requiring “that manufacturers assume direct responsibility for the safety and quality of their products”); *Hobart-Mayfield, Inc. v. National Operating Commission on Standards for Athletic Equipment*, 48 F.4th 656, 669–70 (6th Cir. 2022) (because helmet manufacturer served a “market that places high regard on the safety and warranty of its products,” it had a “legitimate business interest” in “desir[ing] to protect their reputations and sell safe products”); *HDC Medical Inc. v. Minntech Corporation*, 474 F.3d 543, 549–50 (8th Cir. 2007) (since manufacturer could not “predict how its machines would react” to competitors’ solutions, it was right to “believe[] that it could not feasibly warrant the performance of the product”).

1 should consider whether the justification Intuitive offers is the real reason that it imposed the
 2 tying arrangement. A legitimate business purpose is one that benefits the actor regardless of any
 3 harmful effect on competitors, such as a purpose to promote efficiency or quality, offer a better
 4 product or service, or increase short-run profits. This inquiry does not turn on an assessment of
 5 Intuitive’s subjective intent, but instead whether Intuitive’s policies and practices have an
 6 objective justification.

7 You must also consider whether Intuitive’s claimed objective could reasonably
 8 have been realized through substantially less restrictive means.⁴¹ Even if some type of constraint
 9 is necessary to promote a legitimate business interest, Intuitive must not adopt a constraint that is
 10 more restrictive than reasonably necessary to achieve that interest.

11 In determining whether Intuitive’s claimed objective could reasonably have been
 12 achieved through substantially less restrictive means, you may assess such factors as whether
 13 other means to achieve Intuitive’s objective were more or less expensive and more or less
 14 effective than the means chosen by Intuitive.

15 If you find that Intuitive could reasonably have achieved its legitimate business
 16 purpose by substantially less restrictive means, then you may find that there was no business
 17 justification and find for SIS on the tying claim. If you find that the alleged tying arrangement
 18 serves a legitimate business purpose of Intuitive, and that there are not substantially less
 19 restrictive means reasonably available to achieve that purpose, then you must find for Intuitive and
 20 against SIS on the tying claim.

21
 22
 23 ⁴¹ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 2 Section 1 of the Sherman
 24 Act—Tying Arrangements, Instruction 11: Business Justification Defense (AM. BAR ASS’N
 25 ANTITRUST L. SECTION 2016) (modified to add the word “substantially” before “less restrictive
 26 means,” see *Nat’l Collegiate Athletic Ass’n v. Alston*, 594 U.S. 69, 100–101 (2021) (“In this suit,
 27 as in any, the district court had to determine whether the defendants’ agreements harmed
 28 competition and whether any procompetitive benefits associated with their restraints could be
 achieved by ‘substantially less restrictive alternative’ means.”); *Epic Games, Inc. v. Apple, Inc.*,
 67 F.4th 946, 985–86, 990 (9th Cir. 2023) (“[T]his circuit’s test—which the Supreme Court
 approved in *Alston*—requires a ‘substantially less restrictive’ alternative.” (emphasis in original;
 citation omitted))).

1 **C. SIS's Exclusive Dealing Claim**

2 Instruction No. 28 Re Elements of Exclusive Dealing⁴²

3 SIS also claims that Intuitive engaged in unlawful exclusive dealing. Intuitive
4 denies this claim.

5 Exclusive dealing arrangements require a buyer of a product or service to obtain
6 that product or service exclusively from one supplier for a period of time. Exclusive dealing
7 arrangements are analyzed under the rule of reason to determine if they result in a substantial and
8 unreasonable harm to competition in a relevant market. From the standpoint of either the buyer
9 or the seller, exclusive dealing arrangements may have potential procompetitive effects that
10 benefit consumers and that need to be weighed against the potential anticompetitive effects of
11 foreclosing competing suppliers' access to the buyer and the buyer's access to competing
12 suppliers' products and services.

13 To establish that an exclusive dealing arrangement violates the Sherman Act, SIS
14 must establish each of the following elements by a preponderance of the evidence:

15 (1) agreements between Intuitive and its customers that totally foreclose
16 customers from purchasing EndoWrist repair or replacement from competing suppliers;

17 (2) the agreements were an unreasonable restraint of trade that resulted in a
18 substantial adverse effect on competition in the alleged aftermarket for EndoWrist repair and
19 replacement;

20 (3) Intuitive had substantial market power in the alleged aftermarket for
21 EndoWrist repair and replacement;

22 and

23 (4) SIS was injured in its business or property because of the agreements.

24
25
26 ⁴² MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 2 – Section 1 of the Sherman
27 Act—Vertical Restraints, Instruction 5: Elements of Exclusive Dealing (AM. BAR ASS'N
28 ANTITRUST L. SECTION 2016) (modified to remove instructions regarding there being “several
forms” of exclusive dealing arrangements, because the particular alleged exclusive dealing
arrangement has been defined by SIS and thus other examples of exclusive dealing arrangements
are irrelevant in this case).

1 If you find that the evidence is insufficient to prove any one or more of these
2 elements, then you must find for Intuitive and against SIS on SIS's exclusive dealing claim. If
3 you find that the evidence is sufficient to prove all four elements, then you must find for SIS and
4 against Intuitive on SIS's exclusive dealing claim.

1 Instruction No. 29 Re Restrictions on Unauthorized Third-Party Products and Services Are Not
 2 Exclusive Dealing

3 SIS challenges provisions of Intuitive’s contracts with customers that restrict the
 4 use of unauthorized third-party products and services in connection with the da Vinci system as
 5 unlawful exclusive dealing. If the seller of a product or service contractually requires its
 6 customers to buy another product or service either from the seller or from third parties that seller
 7 authorizes, such a contractual provision is not an exclusive dealing arrangement unless third
 8 parties cannot realistically obtain such authorization from the seller. SIS bears the burden of
 9 demonstrating that third parties could not realistically obtain authorization from Intuitive and
 10 hence that third-party authorization was illusory. If you find that SIS fails to meet this
 11 burden, then you must find in favor of Intuitive on SIS’s tying claim.⁴³

12
13
14
15
16
17
18
19
20
21 ⁴³ See *Mozart v. Mercedes-Benz*, 593 F. Supp. 1506, 1517 (N.D. Cal. 1984) (citing *United States*
 22 *v. Mercedes-Benz of N. Am., Inc.*, 517 F. Supp. 1369, 1383–84 (N.D. Cal. 1981)) (where the
 23 defendant asks customers only to work with “authorized” third parties, there is no forcing or
 24 coercion unless the option for third parties to become authorized is “illusory”); see also *Ford*
 25 *Motor v. GMB Universal Joints*, 1988 WL 82826, at *3 (9th Cir. 1988) (“[a]n approval
 26 mechanism must not be illusory”) (unpublished disposition) (citing *Mozart*, 593 F. Supp. at
 27 1517); *Photovest v. Fotomat*, 606 F.2d 704, 722 (7th Cir. 1979) (“Given the contractual
 28 language, which at least provides for the possibility of purchasing processing from non-Fotomat
 sources, we are reluctant to find a tying arrangement without some evidence that Fotomat
 applied the contract language so restrictively as to constitute a de facto tying clause. The
 presence of the illegal condition may be inferred from an extrinsic course of conduct
 supplementing the written contract, but in the present case Photovest has failed to provide
 evidence of any conduct from which to infer the tie.” (quotation marks and internal citation
 omitted)).

Instruction No. 30(a) Re Substantial Adverse Effect on Competition⁴⁴

In determining whether Intuitive's agreements with its customers had a substantially harmful effect on competition in the alleged aftermarket for EndoWrist repair and replacement, you should consider the nature and history of the use of exclusive dealing contracts in the industry, whether buyers of Intuitive's products have independent reasons for entering into exclusive dealing contracts or were coerced into entering into them, whether other competing suppliers also offer exclusive dealing contracts, the extent of competition among competing suppliers for exclusive dealing contracts with buyers, Intuitive's position in the marketplace, the competitive alternatives to Intuitive's products, the reasons Intuitive and its customers entered into the contracts at issue, and the effect of the use of exclusive dealing contracts on the ability of new firms to enter the market and on price and other competition in the market. It is not enough that the conduct at issue has the effect of reducing consumers' choices or increasing prices to consumers.⁴⁵

You also should consider whether the buyer is the final end user of the product. If the buyer is the final end user, the exclusive dealing contract forecloses competitors from that portion of the market represented by the buyer's purchases and makes it more likely that competition may be harmed if the buyer represents a substantial portion of the market. On the other hand, if the buyer is a distributor or reseller, and there are other alternatives for competing sellers to market their products to end users, then an exclusive dealing arrangement may not foreclose competitors' access to the market and, thus, not substantially harm competition.

If you find that Intuitive's contracts did not have a substantial adverse effect on competition in the alleged aftermarket for EndoWrist repair and replacement, then you must find for Intuitive on SIS's exclusive dealing claim. If you find that Intuitive's contracts did have a

⁴⁴ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 2 – Section 1 of the Sherman Act—Vertical Restraints, Instruction 6: Exclusive Dealing – Additional Considerations (AM. BAR ASS'N ANTITRUST L. SECTION 2016).

⁴⁵ Dkt. 204 at 17 (quoting *FTC v. Qualcomm, Inc.*, 969 F.3d 974, 993–94 (9th Cir. 2020) (quoting *Brantley v. NBC Universal, Inc.*, 675 F.3d 1192, 1202 (9th Cir. 2012))).

1 substantial adverse effect on competition in the alleged aftermarket for EndoWrist repair and
2 replacement, then you must assess the other elements of SIS's exclusive dealing claim.

Instruction No. 30(b) Re Substantial Foreclosure of Competition⁴⁶

In determining the extent to which Intuitive’s exclusive dealing contracts foreclosed competition on the merits, it is relevant to consider the percentage of the market foreclosed and the length of the foreclosure. Where the exclusive dealing contracts foreclosed less than 30–40 percent of the market, this indicates that the harm from the foreclosure of competition was not substantial because there are alternatives available. Similarly, the shorter the duration of the contract, the less likely it is to harm competition. The longer the contract’s duration, the more likely that the harm to competition will be greater, unless it is clear that there was vigorous competition on the merits to win the longer contract or the buyer as a practical matter can terminate the agreement on short notice without cause and without significant penalty. In such a case, the stated length of the exclusive contract is not the period in which it has a competitive effect.

⁴⁶ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 2 Section 1 of the Sherman Act—Vertical Restraints, Instruction 6: Exclusive Dealing – Additional Considerations (AM. BAR ASS’N ANTITRUST L. SECTION 2016) (modified to change the threshold from “20 percent” to “30–40 percent,” which is consistent with prevailing caselaw, *see, e.g., Omega Env’t, Inc. v. Gilbarco, Inc.*, 127 F.3d 1157, 1162–65 (9th Cir. 1997) (“Although 38% [foreclosure] appears significant, . . . we conclude that it considerably overstates the size of the foreclosure and its likely anticompetitive effect for several reasons.” (citation and internal quotation marks omitted)); *Sterling Merchandising, Inc. v. Nestle, S.A.*, 656 F.3d 112, 123–24 (1st Cir. 2011) (“[I]n applying the rule of reason calculus to exclusive dealing arrangements, foreclosure levels are unlikely to be of concern where they are less than 30 or 40 percent, and while high numbers do not guarantee success for an antitrust claim, low numbers make dismissal easy.”); *Valley Prods. Co. v. Landmark*, 128 F.3d 398, 402 n.3 (6th Cir. 1997) (federal courts “hav[e] repeatedly held that a 30 percent market share is insufficient to confer . . . market power”); *United States v. Microsoft Corp.*, 87 F. Supp. 2d 30, 52–53 (D.D.C. 2000) (foreclosure rate closer to 40 percent is required before an exclusive contract raises competitive concerns); *Union Carbide Corp. v. Montell N.V.*, 27 F. Supp. 2d 414, 417 (S.D.N.Y. 1998) (foreclosure percentage in the 30 percent range is the point at which firms are “presumptively incapable of exercising market power”); ABA, 1 ANTITRUST LAW DEVELOPMENTS, ch. 1 § D.2 (Vertical Restraints on Interbrand Competition) at n.1432 & accompanying text (“Although foreclosure of 20 to 30 percent was a gray area before *Jefferson Parish [Hospital District No. 2 v. Hyde]*, 466 U.S. 2 (1984), the concurring opinion in *Jefferson Parish*, which found exclusive dealing lawful without detailed analysis when 30 percent of the market was foreclosed, has led many courts to hold that higher market share thresholds are a prerequisite to finding exclusive dealing unlawful--and even then, a finding that the arrangement is anticompetitive is not a foregone conclusion.”).

Instruction No. 32 Re Market Power⁴⁷

To prevail on its exclusive dealing claim, SIS must prove by a preponderance of the evidence that Intuitive had substantial power in the alleged aftermarket for EndoWrist repair and replacement. If Intuitive does not possess market power, then there cannot be substantial harm to competition from Intuitive's contracts, and you must find for Intuitive on this claim.

A firm that possesses market power generally can charge higher prices for the same goods or services that a firm in the same market that does not possess market power. The ability to charge higher prices for better products or services, however, is not market power. An important factor in determining whether Intuitive possesses market power is its market share, that is, its percentage of the products or services sold in the relevant market by all competitors. Other factors that you may consider in determining whether Intuitive has market power include market share trends, the existence of barriers to entry (that is, how difficult is it for other producers to enter the market and begin competing with defendant for sales), the entry and exit by other companies, and the number and size of actual competitors or potential competitors.

If you decide that the buyers are sophisticated businesses themselves which had countervailing power in negotiating contracts, this may offset any market power Intuitive might otherwise have. If SIS cannot show that Intuitive had the power to force buyers to enter into exclusive contracts they did not want, this would be an indication that Intuitive lacks market power.

If you find that SIS has not proved by a preponderance of the evidence that Intuitive possesses substantial market power in the alleged aftermarket for EndoWrist repair and replacement, then you must find for Intuitive on SIS's exclusive dealing claim. If you do find that SIS has proved that Intuitive possesses substantial market power in the alleged aftermarket

⁴⁷ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 2 – Section 1 of the Sherman Act—Vertical Restraints, Instruction 6: Exclusive Dealing – Additional Considerations (AM. BAR ASS'N ANTITRUST L. SECTION 2016); MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 1 Sherman Act—General, Instruction 3B: Rule of Reason – Proof of Competitive Harm (AM. BAR ASS'N ANTITRUST L. SECTION 2016).

1 for EndoWrist repair and replacement, then you must go on to assess the other elements of SIS's
2 exclusive dealing claim.
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

Instruction No. 33 Re Evidence of Competitive Benefits⁴⁸

If you find that SIS has proven that Intuitive’s agreements with its customers constitute exclusive dealing arrangements that resulted in substantial harm to competition in the alleged aftermarket for EndoWrist repair and replacement, then you next must determine whether Intuitive’s agreements also benefit competition in other ways. If you find that the exclusive dealing arrangements do result in competitive benefits, then you also must consider whether those restraints were reasonably necessary to achieve the benefits. If SIS proves that the same benefits could have been readily achieved by other, reasonably available means that create substantially less harm to competition, then they cannot be used to justify the restraint.

Antitrust law does not require businesses like Intuitive to use the least restrictive means of achieving a legitimate business purpose. Any alternative to the challenged conduct presented by SIS must be a substantially—not marginally—less restrictive means for achieving the same procompetitive rationales. A procompetitive rationale is a nonpretextual claim that a defendant’s conduct is indeed a form of competition on the merits because it involves, for example, greater efficiency or enhanced consumer appeal.⁴⁹ To qualify as substantially less restrictive, an alternative means must be virtually as effective in serving the Intuitive’s procompetitive purposes without significantly increased cost.⁵⁰

⁴⁸ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 1 Sherman Act—General, Instruction 3C: Rule of Reason – Evidence of Competitive Benefits (AM. BAR ASS’N ANTITRUST L. SECTION 2016).

⁴⁹ Dkt. 204 at 17 (quoting *FTC v. Qualcomm Inc.*, 969 F.3d 974, 991 (9th Cir. 2020)).

⁵⁰ *Epic Games, Inc. v. Apple, Inc.*, 67 F.4th 946, 990 (9th Cir. 2023) (“When evaluating proposed alternative means, courts must give wide berth to defendants’ business judgments and must resist the temptation to require that enterprises employ the least restrictive means of achieving their legitimate business objectives. . . . As such, this circuit’s test—which the Supreme Court approved in *Alston*—requires a substantially less restrictive alternative.” (quotations omitted) (citing *Alston*, 141 S. Ct. at 2161, 2163 (2021); *id.* (“To qualify as “substantially less restrictive,” an alternative means “must be ‘virtually as effective’ in serving the [defendant’s] procompetitive purposes . . . without significantly increased cost.” (citing *Cnty. of Tuolumne v. Sonora Cmty. Hosp.*, 236 F.3d 1148, 1159 (9th Cir. 2001))).

III. ANTITRUST SECTION 2 OF THE SHERMAN ACT

Instruction No. 34 Re Sherman Act Section 2 Claims

SIS asserts that Intuitive violated Section 2 of the Sherman Act by monopolizing or attempting to monopolize the alleged aftermarket for EndoWrist repair and replacement.⁵¹ I will now instruct you on the elements of each of these claims.

⁵¹ 15 U.S.C. § 2; Complaint (Dkt. 1) ¶¶ 118, 121.

A. Section 2 Monopolization

Instruction No. 35 Re Elements of Monopolization⁵²

SIS alleges that it was injured by Intuitive’s unlawful monopolization of the alleged aftermarket for EndoWrist repair and replacement. To prevail on this claim, SIS must prove each of the following elements by a preponderance of the evidence:

- (1) the alleged aftermarket for EndoWrist repair and replacement is a valid antitrust market;
- (2) Intuitive possessed monopoly power in the alleged aftermarket for EndoWrist repair and replacement;
- (3) Intuitive willfully acquired or maintained monopoly power in the alleged aftermarket for EndoWrist repair and replacement by engaging in anticompetitive conduct; and
- (4) SIS was injured in its business or property because of Intuitive’s anticompetitive conduct.

If you find that SIS has failed to prove any of these elements, then you must find for Intuitive and against SIS on this claim. If you find that SIS has proved each of these elements by a preponderance of the evidence, then you must find for SIS against Intuitive on this claim.

⁵² MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 3 – Section 2 of the Sherman Act—Monopolization—General, Instruction 1: Elements (AM. BAR ASS’N ANTITRUST L. SECTION 2016) (modified to remove the element that the alleged anticompetitive conduct “occurred in or affected interstate commerce,” which is not contested).

1 Instruction No. 36 Re Monopolization – Relevant Product Market

2 I have previously instructed you on the standards for identifying a relevant
3 market. For its monopolization claim, SIS contends that the relevant product market is
4 EndoWrist repair and replacement, while Intuitive contends that SIS has failed to allege the
5 proper relevant product market. If you find that SIS has proven its proposed relevant product
6 market, then you should continue to evaluate the remainder of SIS’s monopolization claim.
7 However, if you find that SIS has failed to prove such a market, then you must find in Intuitive’s
8 favor on this claim.

Instruction No. 37 Re Monopoly Power Defined

To prove its monopolization claim, SIS must prove that Intuitive has monopoly power in the alleged aftermarket for EndoWrist repair and replacement.

Monopoly power is the power to control prices, restrict output, and exclude competition in a relevant antitrust market. More precisely, a firm is a monopolist if it can profitably raise prices substantially above the competitive level for a significant period of time. However, possession of monopoly power, in and of itself, is not unlawful.⁵³ Monopoly power can be lawfully acquired and maintained through growth or development as a consequence of a superior product, business acumen, or historic accident.⁵⁴

I will now provide further instructions about how you may determine whether SIS has met its burden of proving monopoly power in the alleged aftermarket for EndoWrist repair and replacement. There are two ways for SIS to prove that Intuitive had monopoly power in a relevant market. SIS may prove monopoly power through direct evidence of restricted output and supracompetitive prices, or through indirect evidence that Intuitive has a dominant market share in the relevant antitrust market and consideration of other characteristics of the relevant market. I will explain these in turn.⁵⁵

If, after considering the direct and indirect evidence, you find SIS has failed to prove by a preponderance of the evidence that Intuitive has monopoly power in the alleged aftermarket for EndoWrist repair and replacement, then you must find for Intuitive on SIS's monopolization claim. If you find that SIS has proved that Intuitive has monopoly power in the alleged aftermarket for EndoWrist repair and replacement, then you must assess the other elements of SIS's monopolization claim.

⁵³ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 3 Section 2 of the – Sherman Act—Monopolization-General, Instruction 2: Monopoly Power Defined (AM. BAR ASS'N ANTITRUST L. SECTION 2016).

⁵⁴ *Epic Games v. Apple, Inc.*, 67 F.4th 946, 998 (9th Cir. 2023) (“A Section 2 monopolization claim ‘has two elements: (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.’” (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71 (1966))).

⁵⁵ See *infra* Stipulated Jury Instruction No. 34; Stipulated Jury Instruction No. 35.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

Instruction No. 38 Re Monopoly Power – Direct Evidence⁵⁶

One way that SIS may prove monopoly power to control prices and exclude competition is through direct evidence that Intuitive has the ability to raise or maintain the prices that it charges for goods or services in the alleged aftermarket for EndoWrist repair and replacement substantially above the competitive levels for a significant period of time.

SIS has the burden of proving that Intuitive has the ability to raise or maintain the prices that it charges for goods or services in the alleged aftermarket for EndoWrist repair and replacement above competitive levels, and to restrict output in that market.⁵⁷ SIS must prove that Intuitive has the power to do so by itself—that is, without the assistance of, and despite competition from, any existing or potential competitors.

SIS must also prove that Intuitive has the power to maintain prices above a competitive level and restrict output for a significant period of time. If Intuitive attempted to maintain prices above competitive levels, but would lose so much business to other competitors

⁵⁶ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 3 Section 2 of the Sherman Act—Monopolization—General, Instruction 8: Existence of Monopoly Power – Direct Proof (AM. BAR ASS’N ANTITRUST L. SECTION 2016).

⁵⁷ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 3 Section 2 of the Sherman Act—Monopolization—General, Instruction 8: Existence of Monopoly Power – Direct Proof (AM. BAR ASS’N ANTITRUST L. SECTION 2016) (modified to specify that direct proof requires showing supracompetitive prices and restricted output, *see, e.g., Rebel Oil Co., Inc. v. Atl. Richfield Co.*, 51 F.3d 1421, 1434 (9th Cir. 1995) (“Market power may be demonstrated through either of two types of proof. One type of proof is direct evidence of the injurious exercise of market power. If the plaintiff puts forth evidence of restricted output and supracompetitive prices, that is direct proof of the injury to competition which a competitor with market power may inflict, and thus, of the actual exercise of market power.” (citing *FTC v. Ind. Fed’n of Dentists*, 476 U.S. 447, 460–61 (1986))); *Forsyth v. Humana, Inc.*, 114 F.3d 1467, 1475 (9th Cir. 1997) (“Direct proof of market power may be shown by evidence of restricted output and supracompetitive prices.”); *Theme Promotions, Inc. v. News Amer. Mktg. FSI*, 546 F.3d 991, 1001 (9th Cir. 2008) (“Evidence of restricted output and supracompetitive prices is direct evidence of market power . . .”); *Safeway Inc. v. Abbott Lab’ys*, 761 F. Supp. 2d 874, 887 (N.D. Cal. 2011) (“To prove monopoly power directly, supracompetitive pricing must be accompanied by restricted output. . . . Both are required to prove monopoly power directly.”); *CoStar Grp., Inc. v. Com. Real Est. Exch. Inc.*, 2023 WL 2468742, at *5 (N.D. Cal. Feb. 23, 2023) (“[D]irect evidence of the injurious exercise of market power . . . is evidence of restricted output and supracompetitive prices.”); *Epic Games, Inc. v. Apple Inc.*, 559 F. Supp. 3d 898, 1031 (N.D. Cal. 2021) (lack of evidence of restricted output “fatal in demonstrating monopoly power”).

1 that the price increase would become unprofitable and would have to be withdrawn, then
 2 Intuitive does not have monopoly power.

3 Similarly, SIS must prove that Intuitive has the ability to exclude competition. For
 4 example, if Intuitive attempted to maintain prices above competitive levels, but new competitors
 5 could enter the market for EndoWrist repair and replacement or existing competitors could
 6 expand their sales and take so much business that the price increase would become unprofitable
 7 and would have to be withdrawn, then Intuitive does not have monopoly power. The ability to
 8 earn high profit margins or a high rate of return does not necessarily mean that Intuitive has
 9 monopoly power. Other factors may enable a company without monopoly power to sell at higher
 10 prices or earn higher profit margins than its competitors, such as superior products or services,
 11 low costs, or superior advertising or marketing. In analyzing whether supracompetitive pricing
 12 was present, you may also consider Intuitive's total fixed costs, including capital costs and
 13 research and development.⁵⁸ However, an ability to sell at higher prices or earn higher profit
 14 margins than other companies for similar goods or services over a long period of time may be
 15 evidence of monopoly power. By contrast, evidence that Intuitive would lose a substantial
 16 amount of sales if it raised prices substantially, or that Intuitive's profit margins were low
 17 compared to its competitors, or that Intuitive's margins go up and down or are steadily
 18 decreasing, might be evidence that Intuitive does not have monopoly power.

21
 22 ⁵⁸ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 3 Section 2 of the Sherman
 23 Act—Monopolization—General, Instruction 8: Existence of Monopoly Power – Direct Proof
 24 (AM. BAR ASS'N ANTITRUST L. SECTION 2016) (“expand or contract list as appropriate”); *In re*
 25 *Remeron Direct Purchaser Antitrust Litig.*, 367 F. Supp. 2d 675, 681 n.10 (D.N.J. 2005)
 26 (“[W]ithout evidence that sheds light on material factors such as [defendant's] price relative to
 27 its total costs (marginal and fixed) . . . , monopoly power cannot be found as a matter of law.”);
 28 *United States v. Eastman Kodak Co.*, 63 F.3d 95, 109 (2d Cir. 1995) (“Certain deviations
 between marginal cost and price, such as those resulting from high fixed costs, are not evidence
 of market power.”); 2B Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of*
Antitrust Principles and Their Application ¶516g (4th ed. 2014 & Supp. 2021) (“No matter how
 accurately measured, of course, a substantial excess of price over marginal cost does not
 necessarily bring excess returns on investment. A firm generates excess profit only if price
 exceeds its average total cost, including its cost of capital.”).

1 Instruction No. 39 Re Monopoly Power – Indirect Evidence⁵⁹

2 Another way that SIS may prove monopoly power in the alleged aftermarket for
3 EndoWrist repair and replacement is through indirect evidence of monopoly power such as
4 Intuitive’s market share, market share trends, barriers to entry, entry and exit by other
5 companies, and the number and size of other competitors. If this evidence establishes that
6 Intuitive has the power to control prices and exclude competition in the alleged aftermarket for
7 EndoWrist repair and replacement, then you may conclude that Intuitive has monopoly power in
8 the market.

9 *Market Share*

10 The first factor that you should consider is Intuitive’s share of the alleged
11 aftermarket for EndoWrist repair and replacement. Based on the evidence that you have heard
12 about Intuitive’s market share, you should determine Intuitive’s market share as a percentage of
13 total sales in the alleged aftermarket for EndoWrist repair and replacement. Intuitive must have a
14 significant share of the market in order to possess monopoly power.

15 In evaluating whether the percentage of market share supports a finding of
16 monopoly power, you also should consider other aspects of the alleged aftermarket for
17 EndoWrist repair and replacement, such as market share trends, the existence of barriers to entry
18 (that is, how difficult is it for other producers to enter the market and begin competing with
19 Intuitive for sales), the entry and exit by other companies, and the number and size of
20 competitors. Along with Intuitive’s market share, these factors should inform you as to whether
21 Intuitive has monopoly power. The higher the company’s share, the higher the likelihood that a
22 company has monopoly power.

23 A market share below 50 percent is ordinarily not sufficient to support a
24 conclusion that Intuitive has monopoly power. However, if you find that the other evidence
25
26

27 ⁵⁹ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 3 Section 2 of the Sherman
28 Act—Monopolization—General, Instruction 7: Existence of Monopoly Power – Indirect Proof
(AM. BAR ASS’N ANTITRUST L. SECTION 2016).

1 demonstrates that Intuitive does, in fact, have monopoly power despite having a market share
2 below 50 percent, you may conclude that Intuitive has monopoly power.

3 *Market Share Trends*

4 The trend in Intuitive's market share is something you may consider. An
5 increasing market share may strengthen an inference that a company has monopoly power,
6 particularly where that company has a high market share, while a decreasing share might show
7 that a company does not have monopoly power.

8 *Barriers to Entry*

9 You may also consider whether there are barriers to entry into the alleged
10 aftermarket for EndoWrist repair and replacement. Barriers to entry make it difficult for new
11 competitors to enter the market in a meaningful and timely way. Barriers to entry might include
12 intellectual property rights (such as patents or trade secrets), the large financial investment
13 required to build a plant or satisfy governmental regulations, specialized marketing practices, and
14 the reputation of the companies already participating in the market (or the brand name
15 recognition of their products).

16 Evidence of low or no entry barriers may be evidence that Intuitive does not have
17 monopoly power, regardless of Intuitive's market share, because new competitors could enter
18 easily if Intuitive attempted to raise prices or restrict output for a substantial period of time. By
19 contrast, evidence of high barriers to entry along with high market share may support an
20 inference that Intuitive has monopoly power.

21 *Entry and Exit by Other Companies*

22 The history of entry and exit in the alleged aftermarket for EndoWrist repair and
23 replacement may be helpful to consider. Entry of new competitors or expansion of existing
24 competitors may be evidence that Intuitive lacks monopoly power. On the other hand,
25 departures from the market, or the failure of firms to enter the market, particularly if prices and
26 profit margins are relatively high, may support an inference that Intuitive has monopoly power.

1 *Number and Size of Competitors*

2 You may consider whether Intuitive's competitors are capable of effectively
3 competing. In other words, you should consider whether the financial strength, market shares,
4 and number of competitors act as a check on Intuitive's ability to price its products. If Intuitive's
5 competitors are vigorous or have large or increasing market shares this may be evidence that
6 Intuitive lacks monopoly power. On the other hand, if you determine that Intuitive's competitors
7 are weak or have small or declining market shares, this may support an inference that Intuitive
8 has monopoly power.

9 *Conclusion*

10 If you find that SIS has not proved by a preponderance of the evidence, whether through
11 direct evidence or indirect evidence, that Intuitive has monopoly power in the alleged aftermarket
12 for EndoWrist repair and replacement, then you must find for Intuitive and against SIS on SIS's
13 monopolization claim. If you find that SIS has proven by a preponderance of the evidence that
14 Intuitive has monopoly power in the alleged aftermarket for EndoWrist repair and replacement,
15 then you must consider the remaining elements of this claim.
16
17
18
19
20
21
22
23
24
25
26
27
28

1 Instruction No. 40 Re Willful Acquisition or Maintenance of Monopoly Power through
 2 Anticompetitive Conduct⁶⁰

3 The next element SIS must prove is that Intuitive willfully acquired or maintained
 4 monopoly power through anticompetitive acts or practices. Anticompetitive acts are acts, other
 5 than competition on the merits, that have the effect of preventing or excluding competition or
 6 frustrating the efforts of other companies to compete for customers within the alleged
 7 aftermarket for EndoWrist repair and replacement. Harm to competition is to be distinguished
 8 from harm to a single competitor or group of competitors, which does not necessarily constitute
 9 harm to competition. Some examples of harm to competition include increased prices, decreased
 10 production levels, and reduced quality.

11 Mere possession of monopoly power, if lawfully acquired, does not violate the
 12 antitrust laws. The acquisition or maintenance of monopoly power by supplying better products
 13 or services, possessing superior business skills, or because of luck, is not unlawful.

14 A monopolist may compete aggressively without violating the antitrust laws, and
 15 a monopolist may charge monopoly prices without violating the antitrust laws. It is not enough
 16 that the conduct at issue has the effect of reducing consumers' choices or increasing prices to
 17 consumers.⁶¹ A monopolist's conduct only becomes unlawful where it involves anticompetitive
 18 acts.

19 The difference between anticompetitive conduct and conduct that has a legitimate
 20 business purpose can be difficult to determine. This is because all companies have a desire to
 21 increase their profits and increase their market share. These goals are an essential part of a
 22 competitive marketplace, and the antitrust laws do not make these goals—or the achievement of
 23 these goals—unlawful, as long as a company does not use anticompetitive means to achieve
 24 these goals.

25
 26 ⁶⁰ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 3 Section 2 of the Sherman
 27 Act—Monopolization—General, Instruction 9: Willful Acquisition or Maintenance of Monopoly
 28 Power (AM. BAR ASS'N ANTITRUST L. SECTION 2016).

⁶¹ Dkt. 204 at 17 (quoting *FTC v. Qualcomm, Inc.*, 969 F.3d 974, 993–94 (9th Cir. 2020)
 (quoting *Brantley v. NBC Universal, Inc.*, 675 F.3d 1192, 1202 (9th Cir. 2012))).

1 In determining whether Intuitive's conduct was anticompetitive or whether it was
2 legitimate business conduct, you should determine whether the conduct is consistent with
3 competition on the merits, whether the conduct provides benefits to consumers, and whether the
4 conduct would make business sense apart from any effect it has on excluding competition or
5 harming competitors.

6 For example, suppose there are five firms that make printers for home computers
7 and that these printers comprised a relevant product market. Suppose also that Firm A developed
8 a more efficient manufacturing process that allowed it to sell profitably at a lower price than its
9 competitors. If Firm A grew its market share and achieved monopoly power by selling
10 profitably at a lower price, it would not be unlawful for Firm A to achieve monopoly power in
11 this way. Developing more efficient processes and developing the ability to sell profitably at
12 lower prices is competition on the merits and benefits consumers, and it therefore is not
13 anticompetitive conduct even if it has a negative effect on competitors.

14 Similarly, in the same example, suppose Firm B developed and patented a
15 revolutionary new printer and consumers so preferred Firm B's printer that Firm B achieved
16 monopoly power. It would not be unlawful for Firm B to achieve monopoly power in printers in
17 this way. Firm B "built a better mousetrap," which is competition on the merits and benefits
18 consumers, and it therefore is not anticompetitive conduct.

19 By contrast, in the same example, suppose that Firm C makes printers, but Firm C
20 is the world's only manufacturer of computers and that there are barriers to entry into the
21 computer market such that no other firm will be able to enter that market. Suppose also that Firm
22 C altered its computers in such a way that only Firm C's printers would work with its computers,
23 and that the alteration does not improve the design of Firm C's computers or provide any
24 benefits to competition or consumers. The only effect of the alteration is to exclude competing
25 printer makers from the marketplace. It would be unlawful for Firm C to achieve monopoly
26 power in the printer market in this way.

27 As the example shows, the acts or practices that result in the acquisition or
28 maintenance of monopoly power must represent something more than the conduct of business

1 that is part of the normal competitive process or commercial success. They must represent
2 conduct that has made it very difficult or impossible for competitors to compete and that was
3 taken for no legitimate business reason. You may not find that a company willfully acquired or
4 maintained monopoly power through anticompetitive means if it has acquired or maintained that
5 power solely through the exercise of superior foresight and skill; or because of natural
6 advantages such as unique geographic access to raw materials or markets; or because of
7 economic or technological efficiency, including efficiency resulting from scientific research; or
8 by obtaining a lawful patent; or because changes in cost or consumer preference have driven out
9 all but one supplier.

10 If you find that SIS has failed to prove by a preponderance of the evidence that
11 Intuitive willfully acquired or maintained monopoly power in the alleged aftermarket for
12 EndoWrist repair and replacement through anticompetitive acts, then you must find for
13 Intuitive on SIS's monopolization claim. If, however, you find that SIS has proven this element
14 by a preponderance of the evidence, then you must consider whether SIS has proved the
15 remaining elements of this claim. .

Instruction No. 41 Re Design Changes

Intuitive had no duty to design or redesign its products in a way that made it easier for third parties to provide their services, and the antitrust laws allow Intuitive to introduce legitimate design changes in its products and phase out older models in favor of new models.⁶² A design change that improves a product by providing a benefit to consumers does not violate the antitrust laws absent some other anticompetitive conduct.⁶³ The antitrust laws necessarily tolerate product improvements, as such improvements serve the very purpose of the antitrust laws, which is to foster and ensure competition on the merits.⁶⁴ An antitrust challenge to a product design change therefore must fail if the design change is an improvement, unless the monopolist abuses or leverages its monopoly power in some other way when introducing the product.⁶⁵

SIS contends that Intuitive violated the antitrust laws by introducing new versions of its da Vinci systems, the X and Xi, that require use of X/Xi EndoWrists with wireless chip technology. Intuitive contends that the switch from S/Si to X/Xi technology improved its products and provides numerous benefits to surgeons and patients. If you find that Intuitive's

⁶² *Cal. Comp. Prods., Inc. v. Int'l Bus. Machs. Corp.*, 613 F.2d 727, 744 (9th Cir. 1979) ("IBM, assuming it was a monopolist, had the right to redesign its products to make them more attractive to buyers whether by reason of lower manufacturing cost and price or improved performance. It was under no duty to help CalComp or other peripheral equipment manufacturers survive or expand. IBM need not have provided its rivals with disk products to examine and copy, nor have constricted its product development so as to facilitate sales of rival products. The reasonableness of IBM's conduct in this regard did not present a jury issue.").

⁶³ *Allied Orthopedic Appliances, Inc. v. Tyco Health Care Grp. LP*, 592 F.3d 991, 998–1002 (9th Cir. 2010) ("If a monopolist's design change is an improvement, it is necessarily tolerated by the antitrust laws, unless the monopolist abuses or leverages its monopoly power in some other way when introducing the product. To hold otherwise would be contrary to the very purpose of the antitrust laws, which is, after all, to foster and ensure competition on the merits." (citations omitted)).

⁶⁴ *Allied Orthopedic Appliances*, 592 F.3d at 998–1002.

⁶⁵ *Allied Orthopedic Appliances*, 592 F.3d at 998–1002; *Foremost Pro Color, Inc. v. Eastman Kodak Co.*, 703 F.2d 534, 545–46 (9th Cir. 1983) ("[P]roduct introduction must be alleged to involve some associated conduct which constitutes an anticompetitive abuse or leverage of monopoly power, or a predatory or exclusionary means of attempting to monopolize the relevant market, rather than aggressive competition on the merits.").

1 introduction of X and Xi systems was a product improvement, then you cannot consider that to
2 be unlawful or anticompetitive conduct.

B. Section 2 Attempted Monopolization

Instruction No. 42 Re Attempted Monopolization – Elements⁶⁶

In addition to alleging monopolization, SIS also alleges that it was injured by Intuitive's unlawful attempt to monopolize the alleged aftermarket for EndoWrist repair and replacement. To prevail on its claim of attempted monopolization, SIS must prove each of the following elements by a preponderance of the evidence:

- (1) Intuitive engaged in anticompetitive conduct;
- (2) Intuitive had a specific intent to achieve monopoly power in the alleged aftermarket for EndoWrist repair and replacement;
- (3) there was a dangerous probability that Intuitive would achieve its goal of monopoly power in the alleged aftermarket for EndoWrist repair and replacement; and
- (5) SIS was injured in its business or property by Intuitive's anticompetitive conduct.

If you find that the evidence is insufficient to prove any one or more of these elements, then you must find for Intuitive and against SIS on SIS's claim of attempted monopolization. If you find that the evidence is sufficient to prove all four elements as to Intuitive, then you must find for SIS and against Intuitive on SIS's claim of attempted monopolization.

⁶⁶ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 3 – Section 2 of the Sherman Act—Attempt to Monopolize, Instruction 1: Elements (AM. BAR ASS'N ANTITRUST L. SECTION 2016) (modified to remove the element that the alleged anticompetitive conduct “occurred in or affected interstate commerce,” which is not contested).

1 Instruction No. 43 Re Attempted Monopolization - Anticompetitive Conduct⁶⁷

2 It is not sufficient for SIS to prove that Intuitive intended to monopolize the
3 alleged aftermarket for EndoWrist repair and replacement. SIS must also show that Intuitive
4 engaged in anticompetitive conduct, coupled with an intent to monopolize and a dangerous
5 probability that Intuitive would succeed. Generally, a firm engages in anticompetitive conduct
6 when it attempts to exclude rivals without an efficiency-enhancing justification for its conduct.

7 I have already instructed you on the standards for determining whether Intuitive
8 engaged in anticompetitive conduct in the context of SIS's monopolization claim. You should
9 apply that same instruction here in the context of determining whether Intuitive engaged in
10 anticompetitive conduct in connection with SIS's allegations that Intuitive attempted to
11 monopolize the alleged aftermarket for EndoWrist repair and replacement.

12 If you find SIS has failed to prove by a preponderance of the evidence that
13 Intuitive engaged in anticompetitive conduct in the alleged aftermarket for EndoWrist repair and
14 replacement, then you must find for Intuitive on SIS's monopolization claim. If you find that
15 SIS has proved that Intuitive engaged in anticompetitive conduct, then you must assess the other
16 elements of SIS's attempted monopolization claim.

17
18
19
20
21
22
23
24
25
26
27 _____
28 ⁶⁷ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 3 – Section 2 of the Sherman
Act—Attempt to Monopolize, Instruction 2: Anticompetitive Conduct (AM. BAR ASS'N
ANTITRUST L. SECTION 2016).

Instruction No. 44 Re Specific Intent to Achieve Monopoly Power⁶⁸

SIS must prove that Intuitive had a specific intent to monopolize a relevant market. To do so, SIS must first prove that the aftermarket SIS is talking about—EndoWrist repair and replacement—is a relevant market for antitrust purposes. SIS must then prove that Intuitive had a specific intent to monopolize that market.

The court has already provided you with instructions on determining whether the alleged aftermarket for EndoWrist repair and replacement is a relevant market. If SIS proves that the aftermarket for EndoWrist repair and replacement is a relevant market, you must then decide whether Intuitive had the specific intent to monopolize that market. In other words, you must decide if the evidence shows that Intuitive acted with the conscious aim of acquiring the power to control prices and to exclude or destroy competition in the aftermarket for EndoWrist repair and replacement.

There are several ways in which SIS may prove that Intuitive had the specific intent to monopolize. There may be evidence of direct statements of Intuitive's intent to obtain a monopoly in the aftermarket for EndoWrist repair and replacement. Such proof of specific intent may be established by documents prepared by responsible officers or employees of Intuitive at or about the time of the conduct in question or by testimony concerning statements made by responsible officers or employees of Intuitive. You must be careful, however, to distinguish between a defendant's lawful intent to compete aggressively, which may be accompanied by aggressive language, and a true intent to acquire monopoly power by using anticompetitive means.

Even if you decide that the evidence does not prove directly that Intuitive actually intended to obtain a monopoly, specific intent may be inferred from what Intuitive did. For example, if the evidence shows that Intuitive lacked a legitimate business justification and the natural and probable consequence of Intuitive's conduct in the aftermarket for EndoWrist repair

⁶⁸ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 3 – Section 2 of the Sherman Act—Attempt to Monopolize—Instruction 3: Specific Intent (AM. BAR ASS'N ANTITRUST L. SECTION 2016).

1 and replacement was to give Intuitive control over prices and to exclude or destroy competition,
2 and that this was plainly foreseeable by Intuitive, then you may (but are not required to) infer
3 that Intuitive specifically intended to acquire monopoly power.

4 In this case, SIS argues that the conduct underlying the claim of attempt to
5 monopolize also constitutes an unreasonable restraint of trade under Section 1 of the Sherman
6 Act. If you find on that SIS has proven Intuitive restrained trade in the aftermarket for EndoWrist
7 repair and replacement under the instructions you have received pertaining to Section 1 of the
8 Sherman Act, then you may infer from such conduct that Intuitive had the specific intent to
9 achieve monopoly power.

10 If you find that SIS failed to prove by a preponderance of the evidence either that
11 the alleged aftermarket for EndoWrist repair and replacement is not a relevant market, or that
12 Intuitive did not have a specific intent to monopolize that market, then you must find for
13 Intuitive on SIS's attempted monopolization claim. If you find that SIS has proved by a
14 preponderance of the evidence both the existence of the relevant market and Intuitive's specific
15 intent to monopolize that market, then you must go on to assess the other elements of SIS's
16 attempted monopolization claim.

1 Instruction No. 45 Re Dangerous Probability of Success⁶⁹

2 If you find that Intuitive had the specific intent to achieve a monopoly in the
3 alleged aftermarket for EndoWrist repair and replacement and engaged in significant
4 anticompetitive conduct, you also must determine if the evidence shows the next element of
5 attempt to monopolize: namely, that there was a dangerous probability that Intuitive would
6 succeed in achieving monopoly power if it continued to engage in the same or similar conduct.

7 I have already defined monopoly power for you in Instruction No. 37. You
8 should use that same instruction to evaluate this element of SIS's attempted monopolization
9 claim. In determining whether there was a dangerous probability that Intuitive would acquire the
10 ability to control price in the market, you should consider such factors as:

- 11 • Intuitive's market share;
- 12 • the trend in Intuitive's market share;
- 13 • whether the barriers to entry into the market made it difficult for
- 14 competitors to enter the market;
- 15 • the likely effect of any anticompetitive conduct on Intuitive's share of the
- 16 market.

17 Again, the purpose of looking at these and other factors is to determine whether
18 there was a dangerous probability that Intuitive would ultimately acquire monopoly power. A
19 dangerous probability of success need not mean that success was nearly certain, but it does mean
20 that there was a substantial and real likelihood that Intuitive would ultimately acquire monopoly
21 power. Thus, even if you find that Intuitive intended to create a monopoly, you may not find that
22 Intuitive attempted to monopolize if you find that it was not possible for Intuitive to achieve its
23 goal.

24 If you find that SIS failed to prove by a preponderance of the evidence that there
25 was a dangerous probability that Intuitive would succeed in achieving monopoly power in the
26

27 _____
28 ⁶⁹ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 3 Section 2 of the Sherman
Act—Attempt to Monopolize—Instruction 4: Dangerous Probability of Success (AM. BAR ASS'N
ANTITRUST L. SECTION 2016).

1 alleged aftermarket for EndoWrist repair and replacement, then you must find for Intuitive on
2 SIS's attempted monopolization claim. If, however, you find that SIS proved by a
3 preponderance of the evidence that there was a dangerous probability that Intuitive would
4 succeed in achieving monopoly power, then you must go on to assess the other elements of SIS's
5 attempted monopolization claim.

1 **IV. ANTITRUST INJURY & DAMAGES**

2 Instruction No. 46 Re Injury⁷⁰

3 If you find that SIS has met its burden on each of the other elements of any of its
4 claims, as I have described them to you, then you must finally decide if SIS is entitled to recover
5 damages from Intuitive.

6 SIS is entitled to recover damages for an injury to its business or property if it can
7 establish three elements of injury and causation:

- 8 (1) SIS was in fact injured as a result of Intuitive's alleged violation of the
9 antitrust laws;
- 10 (2) Intuitive's alleged illegal conduct was a material cause of SIS's injury;
11 and
- 12 (3) SIS's injury is an injury of the type that the antitrust laws were intended to
13 prevent.
- 14
15
16
17
18
19
20
21
22
23
24
25
26

27 _____
28 ⁷⁰ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 6 Causation and Damages
Clayton Act Section 4 Requirements, Instruction 1: Injury and Causation (AM. BAR ASS'N
ANTITRUST L. SECTION 2016).

1 Instruction No. 47 Re Injury in Fact⁷¹

2 The first element is sometimes referred to as “injury in fact” or “fact of damage.”
3 For SIS to establish that it is entitled to recover damages, it must prove that it was injured as a
4 result of Intuitive’s alleged violation of the antitrust laws. Proving the fact of damage does not
5 require SIS to prove the dollar value of its injury. It requires only that SIS prove that it was in
6 fact injured by Intuitive’s alleged antitrust violation.
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26

27 _____
28 ⁷¹ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 6 – Causation and Damages
– Clayton Act Section 4 Requirements, Instruction 1: Injury and Causation (AM. BAR ASS’N
ANTITRUST L. SECTION 2016).

1 Instruction No. 48 Re Causation⁷²

2 SIS must also offer evidence that establishes by a preponderance of the evidence
3 that Intuitive's alleged illegal conduct was a material cause of SIS's injury. This means that SIS
4 must have proved that some damage occurred to it as a result of Intuitive's alleged antitrust
5 violation, and not some other cause. SIS is not required to prove that Intuitive's alleged antitrust
6 violation was the sole cause of its injury; nor need SIS eliminate all other possible causes of
7 injury. It is enough if SIS has proved that the alleged antitrust violation was a material cause of
8 its injury. However, if you find that SIS's injuries were caused primarily by factors other than
9 the alleged antitrust violation, then the causation element is not satisfied.⁷³

10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26 _____
27 ⁷² MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 6 – Causation and Damages
– Clayton Act Section 4 Requirements, Instruction 1: Injury and Causation (AM. BAR ASS'N
ANTITRUST L. SECTION 2016).

28 ⁷³ *Discover Fin. Servs. v. Visa U.S.A., Inc.*, 582 F. Supp. 2d 501, 504–05 (S.D.N.Y. 2008) (citing
ABA Section of Antitrust Law, Model Jury Instructions in Civil Antitrust Cases (2005) at F–3)

1 Instruction No. 49 Re Antitrust Injury⁷⁴

2 Finally, SIS must establish that its injury is the type of injury that the antitrust
3 laws were intended to prevent. This is sometimes referred to as “antitrust injury.” If SIS’s
4 injuries were caused by a reduction in competition, acts that would lead to a reduction in
5 competition, or acts that would otherwise harm consumers, then SIS’s injuries are antitrust
6 injuries. On the other hand, if SIS’s injuries were caused by heightened competition, the
7 competitive process itself, or by acts that would benefit consumers, then SIS’s injuries are not
8 antitrust injuries and SIS may not recover damages for those injuries under the antitrust laws.

9 You should bear in mind that businesses may incur losses for many reasons that
10 the antitrust laws are not designed to prohibit or protect against—such as where a competitor
11 offers better products or services, or where a competitor is more efficient and can charge lower
12 prices and still earn a profit. The antitrust laws do not permit SIS to recover damages for losses
13 that were caused by the competitive process or conduct that benefits consumers.

14 In summary, if SIS can establish that it was in fact injured by Intuitive’s conduct,
15 that Intuitive’s conduct was a material cause of SIS’s injury, and that Intuitive’s injury was the
16 type that the antitrust laws were intended to prevent, then SIS is entitled to recover damages for
17 the injury to its business or property.

18
19
20
21
22
23
24
25
26
27
28 ⁷⁴ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 6 – Causation and Damages
– Clayton Act Section 4 Requirements, Instruction 1: Injury and Causation (AM. BAR ASS’N
ANTITRUST L. SECTION 2016).

1 Instruction No. 50 Re Damages for Competitors--Preparedness to Enter Business⁷⁵

2 SIS claims that it was harmed because Intuitive's alleged antitrust violation
3 prevented it from entering a new line of business: repair of EndoWrists. To recover damages, it is
4 not necessary that SIS actually have entered into this business if you find that Intuitive's alleged
5 antitrust violation prevented SIS from entering into this business. SIS must prove, however, that
6 it had an intention to enter into this business and that it had taken concrete steps to prepare to do
7 so.

8 In determining whether or not SIS has demonstrated the intention and
9 preparedness to enter this new business, you may consider such elements as the following: the
10 background and experience of the principals and employees of SIS; the ability of SIS to finance
11 the new line of business and to purchase the necessary facilities and equipment; and concrete and
12 discernible steps taken by SIS to enter into this new line of business. Ultimately, to award SIS
13 damages related to its failure to enter this business, you must determine that had it not been for
14 Intuitive's alleged antitrust violation, SIS would have entered that business of repairing
15 EndoWrists.

16
17
18
19
20
21
22
23
24
25
26
27
28 ⁷⁵ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 6 – Causation and Damages
– Clayton Act Section 11 Damages for Competitors—Preparedness to Enter Business (AM. BAR
ASS'N ANTITRUST L. SECTION 2016).

1 Instruction No. 51 Re FDA Clearance

2 You have heard testimony in this case about FDA 510(k) clearance. I will now
 3 instruct you on the law that applies to this subject. Medical devices are regulated under the
 4 Food, Drug, and Cosmetic Act, which Congress enacted to protect consumers from harmful
 5 products.⁷⁶ The products at issue in this case are considered to be medical devices.⁷⁷ The FDA
 6 has identified these medical devices and the surgical instruments used with them as “computer-
 7 controlled surgical instrument systems.”⁷⁸ All computer-controlled surgical instrument systems
 8 and the instruments used with them, including those that are remanufactured, are required to be
 9 approved or cleared by the FDA.⁷⁹ The FDA considers a device to be remanufactured when it
 10 has been subject to any act that results in a significant change to the device’s performance, safety
 11 specifications, or intended use, as compared to the device that was originally approved or cleared
 12 by the FDA.⁸⁰ If you conclude that the insertion of a memory chip into an EndoWrist to change
 13 its usage limit is remanufacturing as defined by the FDA, you must find that SIS could not
 14 lawfully perform that operation on an instrument to be used for human surgery unless it obtained
 15 510(k) clearance from FDA to perform that action on that particular EndoWrist.

16
17
18
19
20
21
22
23
24 _____
 25 ⁷⁶ *Wyeth v. Levine*, 555 U.S. 555, 574 (2009); FDCA § 301(a)-(c), 21 U.S.C. § 331(a)-(c).

26 ⁷⁷ 21 C.F.R. § 876.1500 (product code NAY).

27 ⁷⁸ 21 C.F.R. § 876.1500 (product code NAY).

28 ⁷⁹ FDCA § 510(k), 21 U.S.C. § 360(k); FDCA § 301(p), 21 U.S.C. § 331(p); FDCA § 502(o), 21 U.S.C. § 352(o); 21 C.F.R. § 807.81.

⁸⁰ 21 C.F.R. § 820.3(w) (“Remanufacturer means any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device’s performance or safety specifications, or intended use.”).

1 Instruction No. 52 Re Antitrust Damages -- Introduction and Purpose⁸¹

2 If you find that Intuitive violated the antitrust laws and that this violation caused
3 injury to SIS, then you must determine the amount of damages, if any, SIS is entitled to recover.

4 The fact that I am giving you instructions concerning the issue of SIS's damages
5 does not mean that I believe SIS should, or should not, prevail in this case. If you reach a verdict
6 for Intuitive on the issue of liability, you should not consider the issue of damages, and you may
7 disregard the damages instruction that I am about to give.

8 The law provides that SIS should be fairly compensated for all damages to its
9 business or property that were a direct result or likely consequence of the conduct that you have
10 found to be unlawful.

11 Antitrust damages are only compensatory, meaning their purpose is to put an
12 injured plaintiff as near as possible in the position in which it would have been had the alleged
13 antitrust violation not occurred. The law does not permit you to award damages to punish a
14 wrongdoer—what we sometimes refer to as punitive damages—or to deter particular conduct in
15 the future. Furthermore, you are not permitted to award to SIS an amount for attorneys' fees or
16 the costs of maintaining this lawsuit.

17
18
19
20
21
22
23
24
25
26
27

⁸¹ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 6 – Causation and Damages
28 – Damages, Instruction 1: Antitrust Damages – Introduction and Purpose (AM. BAR ASS'N
ANTITRUST L. SECTION 2016).

1 Instruction No. 53 Re Basis for Calculating Damages⁸²

2 You are permitted to make just and reasonable estimates in calculating SIS's
3 damages. You are not required to calculate damages with mathematical certainty or precision.
4 However, the amount of damages must have a reasonable basis in the evidence and must be
5 based on reasonable, non-speculative assumptions and estimates. Damages may not be based on
6 guesswork or speculation. SIS must prove the reasonableness of each of the assumptions upon
7 which the damages calculation is based.

8 If you find that SIS has provided a reasonable basis for determining damages,
9 then you may award damages based on a just and reasonable estimate supported by the evidence.

10 If you find that SIS has failed to carry its burden of providing a reasonable basis
11 for determining damages, then you may not award damages, or you may award nominal damages
12 not to exceed one dollar.

13
14
15
16
17
18
19
20
21
22
23
24
25
26
27 _____
28 ⁸² MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 6 – Causation and Damages
– Damages, Instruction 3: Basis for Calculating Damages (AM. BAR ASS'N ANTITRUST L.
SECTION 2016).

1 Instruction No. 54 Re Causation and Disaggregation⁸³

2 If you find that Intuitive violated the antitrust laws and that SIS was injured by
3 that violation, SIS is entitled to recover for such injury that was the direct result or likely
4 consequence of the unlawful acts of Intuitive. SIS bears the burden of showing that its injuries
5 were caused by Intuitive's antitrust violation, as opposed to any other factors. If you find that
6 SIS's alleged injuries were caused in part by Intuitive's alleged antitrust violation and in part by
7 other factors, then you may award damages only for that portion of SIS's alleged injuries that
8 was caused by Intuitive's alleged antitrust violation.

9 SIS claims that it suffered injury because it lost sales and profits as a result of
10 Intuitive's alleged violations of the antitrust laws. Intuitive claims that any profits or sales lost
11 by SIS occurred as a result of other factors that have nothing to do with the alleged antitrust
12 violations. These include SIS's failure to seek and obtain clearance from the FDA or
13 authorization from Intuitive to sell modified EndoWrists; SIS's reliance on Rebotix to provide
14 parts and services, rather than developing its own processes; SIS's lack of preparedness to launch
15 a business based on "resetting" X/Xi EndoWrists, as opposed to S/Si EndoWrists; and preference
16 by customers for purchasing EndoWrists from the original manufacturer for patient safety,
17 regulatory, and liability concerns. SIS is not entitled to recover for lost profits that resulted
18 solely from these or other causes arising from the normal course of business activity.⁸⁴ The
19 presence of these factors does not mean SIS did not suffer antitrust injury, but SIS is not entitled
20 to recovery for damages caused by them. SIS only may recover for damages caused by the
21 alleged antitrust violations.

22 SIS bears the burden of proving damages by a preponderance of the evidence,
23 including apportioning damages between lawful and unlawful causes. If you find that SIS has
24

25 ⁸³ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 6 – Causation and Damages
26 – Damages, Instruction 4: Causation and Disaggregation (AM. BAR ASS'N ANTITRUST L.
SECTION 2016).

27 ⁸⁴ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 6 – Causation and Damages
28 – Damages, Instruction 4: Causation and Disaggregation (AM. BAR ASS'N ANTITRUST L.
SECTION 2016) ("list, as appropriate, defendant's examples of ways plaintiff could lose sales in
the normal course of competitive business activity").

1 not established a reasonable basis to apportion its alleged injuries between lawful and unlawful
2 causes, or that apportionment can only be accomplished through speculation or guesswork, then
3 you may not award any damages at all. If you find that the SIS was injured by Intuitive's alleged
4 antitrust violations, and there is a reasonable basis to apportion its alleged injuries between
5 lawful and unlawful causes, then you may award damages.

1 Instruction No. 55 Re Damages for Competitors -- Lost Profits⁸⁵

2 SIS claims that it was harmed because it lost profits as a result of Intuitive's
3 alleged antitrust violation. If you find that Intuitive committed an antitrust violation and that this
4 violation caused injury to SIS, you now must calculate the profits, if any, that SIS lost as a result
5 of Intuitive's antitrust violation. To calculate lost profits, you must calculate net profit: the
6 amount by which plaintiff's gross revenues would have exceeded all of the costs and expenses
7 that would have been necessary to produce those revenues.

8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28 ⁸⁵ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 6 – Causation and Damages
– Damages, Instruction 8: Damages for Competitors – Lost Profits (AM. BAR ASS'N ANTITRUST
L. SECTION 2016).

Instruction No. 56 Re Damages for Competitors -- Future Lost Profits⁸⁶

SIS claims that it was harmed because, had it not been for Intuitive's alleged antitrust violation, SIS would have earned profits into the future, through 2025. If you find that Intuitive committed an antitrust violation and that this violation caused injury to SIS, you now must calculate the future profits, if any, that SIS lost as a result of Intuitive's antitrust violation.

To calculate future lost profits, you must make a reasonable estimate of (1) the amount of profits, if any, that SIS would have earned in future years, and (2) the length of time for which it would have earned those profits. In making this calculation, you are not required to calculate future lost profits with absolute mathematical certainty or precision, but you must not engage in guesswork or speculation. In making this determination, you must consider the various factors that could affect the future success of SIS's business, such as general market or economic conditions, lawful competition SIS would face in the future, SIS's management of business, changes in technology or other business conditions, and other factors affecting SIS's future performance.

Your determination of future lost profits must have a reasonable basis in the evidence and cannot be speculative. If there is no evidence from which you can make a reasonable estimate of lost future profits, you may not award damages for future lost profits.

In calculating future lost profits, you must calculate net profit. In simple terms, net profit is gross revenues minus all of the costs and expenses that would be necessary to produce those revenues.

If you award damages for future lost profits, you must discount the amount to its present value, using a discount rate of interest that you find reasonable. This is because the right to receive a certain sum of money at a future date is worth less than the same amount of money in hand today—this is known as the time value of money. For example, if you had a choice to receive \$1,000 today or a year from now, you would be better off receiving the money today and

⁸⁶ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 6 – Causation and Damages – Damages, Instruction 9: Damages for Competitors – Future Lost Profits (AM. BAR ASS'N ANTITRUST L. SECTION 2016).

1 earning interest on it for a year—you would then have something more than \$1,000 in a year
2 from now. Similarly, if you had a right to \$1,000 a year from now and you asked for the money
3 today, the person owing you the money a year from now could properly give you a lower
4 amount, reflecting the value that could be earned on that money over the next year. This lower
5 amount is known as an amount discounted to present value. The rate of return to be applied in
6 determining present value should be the interest that can reasonably be expected from safe
7 investments that can be made by a person of ordinary prudence, who has ordinary financial
8 experience and skill.⁸⁷

9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28 ⁸⁷ MANUAL OF MODEL CIVIL JURY INSTRUCTIONS FOR THE DISTRICT COURTS OF THE NINTH
CIRCUIT § 5.4 (9th Cir. Jury Instructions Comm. 2017 ed.).

Instruction No. 57 Re Mitigation of Damages⁸⁸

SIS may not recover damages for any portion of its injuries that it could have avoided through the exercise of reasonable care and prudence. SIS is not entitled to increase any damages through inaction. The law requires an injured party to take all reasonable steps it can to avoid further injury and thereby reduce its loss. If SIS failed to take reasonable steps available to it, and the failure to take those steps resulted in greater harm to SIS than it would have suffered had it taken those steps, then SIS may not recover any damages for that part of the injury it could have avoided.

Intuitive has the burden of proof on this issue. Intuitive must prove by a preponderance of the evidence that SIS:

- (1) acted unreasonably in failing to take specific steps to minimize or limit its losses;
- (2) that the failure to take those specific steps resulted in its losses being greater than they would have been had it taken such steps; and
- (3) the amount by which SIS's loss would have been reduced had SIS taken those steps.

In determining whether SIS failed to take reasonable measures to limit its damages, you must remember that the law does not require SIS to take every conceivable step that might reduce its damages. The evidence must show that SIS failed to take commercially reasonable measures that were open to it. Commercially reasonable measures mean those measures that a prudent businessperson in SIS's position would likely have adopted, given the circumstances as they appeared at that time. SIS should be given wide latitude in deciding how to handle the situation, so long as what SIS did was not unreasonable in light of the existing circumstances.

⁸⁸ MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, Chapter 6 – Causation and Damages – Damages, Instruction 14: Mitigation (AM. BAR ASS'N ANTITRUST L. SECTION 2016).

V. INTUITIVE’S COUNTERCLAIMS

Instruction No. 58 Re Intuitive’s Counterclaims

Now, I will instruct you on the law regarding Intuitive’s counterclaims against SIS.

Intuitive brings a claim against SIS under the federal Lanham Act, 15 U.S.C. § 1125, based on false advertising unfair competition.⁸⁹

Intuitive also brings two claims against SIS under California law: one for unfair competition under California’s common law, and one for intentional interference with contractual relations under California’s common law.⁹⁰

I will discuss each of these claims in turn.

⁸⁹ Answer (Dkt. 75) p. 39, Counterclaims ¶ 85.

⁹⁰ Answer (Dkt. 75) p. 39, Counterclaims ¶¶ 102, 106.

A. Lanham Act

Instruction No. 59 Re Lanham Act – Elements of False Statement Claim

Intuitive claims that SIS is liable for false advertising under the Lanham Act, 15 U.S.C. § 1125. Specifically, Intuitive alleges that in its marketing materials and communications disseminated to potential and actual customers, SIS has made numerous false and misleading statements, including but not limited to statements that misrepresent: (i) the nature, efficacy, and/or safety of the service SIS coordinates; (ii) that “repaired” EndoWrists meet applicable quality and functional requirements; (iii) that devices “serviced” through SIS had been repaired to meet “original specifications” of EndoWrists and are safe to use; (iv) that SIS itself developed, has tested and conducts the “repairs;” (v) that use of the service will result in substantial cost savings; (vi) that use of the service does not carry any adverse financial, legal or other consequences (*e.g.*, voiding Intuitive customers’ warranties); (vii) that use limits built into EndoWrists are “arbitrary” or Intuitive otherwise is not trustworthy; and (viii) that SIS and/or the “repair” service is authorized, approved, or endorsed by Intuitive.⁹¹ Intuitive further alleges that customer confusion as to the source or affiliation of the “repaired” instruments is exacerbated by SIS’s communications that misinform customers that “a repaired EndoWrist® is not an alternative or replacement device,” but rather “an original da Vinci® manufactured device that has been repaired to original specifications.”⁹²

To prevail on its claim for false advertising under the Lanham Act, Intuitive must prove by a preponderance of the evidence:

1. SIS’ advertisements were false or misleading;
2. SIS’s advertisements deceived, or had the capacity to deceive, customers;
3. The deception had a material effect on purchasing decisions, meaning that it was likely to influence customers’ purchasing decisions;
4. The misrepresentation affected interstate commerce; and

⁹¹ Answer (Dkt. 75) Counterclaims ¶ 85.

⁹² Answer (Dkt. 75) Counterclaims ¶ 86.

1 5. Intuitive has been injured as a result of the false advertising.⁹³

2 If you find that the evidence is insufficient to prove any one or more of these
3 elements, then you must find for SIS and against Intuitive on Intuitive's false advertising claim.
4 If you find that the evidence is sufficient to prove all of the elements, then you must find for
5 Intuitive and against SIS on Intuitive's false advertising claim.
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24

25 ⁹³ *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1136 (9th Cir. 1997); *Newcal Indus.*,
26 *Inc. v. Ikon Office Solution*, 513 F.3d 1038, 1052 (9th Cir. 2008); FED. CIVIL JURY INSTRUCTIONS
27 OF THE SEVENTH CIRCUIT § 13.3.1 (Committee on Pattern Civil Jury Instructions 7th Cir. 2017
28 ed.); PATTERN JURY INSTRUCTIONS OF THE ELEVENTH CIRCUIT § 10.8 (Committee on Pattern Jury
Instructions 11th Cir. 2024 ed.); MANUAL OF MODEL CIVIL JURY INSTRUCTIONS FOR THE
DISTRICT COURTS OF THE EIGHTH CIRCUIT § 21.43 (Committee on Model Jury Instructions 8th
Cir. 2023 ed.).

1 Instruction No. 60 Re False or Misleading

2 There are two ways in which SIS's advertisements may be false or misleading:
3 they may be literally false, or they may be literally true but misleading. If an advertisement is
4 literally false, then it is presumed to deceive, or to have the capacity to deceive, customers, and
5 Intuitive need not prove that deception.⁹⁴ When evaluating whether an advertising statement is
6 literally false, the statement must be analyzed in its full context.⁹⁵

7 If you find that Intuitive has proved that SIS made false or misleading statements,
8 then you must assess the other elements of Intuitive's false advertising claim. If you find that
9 Intuitive has not proved that SIS made false or misleading statements, then you must find for SIS
10 on Intuitive's false advertising claim.

11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26 ⁹⁴ *Appliance Recycling Ctrs. of Am., Inc. v. JACO Environmental, Inc.*, 378 F. App'x 652, 655
27 (9th Cir. 2010) (citing *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1140 (9th Cir.
28 1997)) (endorsing presumption of deception for literally false statements); *AECOM Energy & Constr., Inc. v. Morrison Knudsen Corp.*, 748 F. App'x 115, 119 (9th Cir. 2018) ("Because [the statements] are literally false, we need not consider the impact on the buying public.").

⁹⁵ *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir. 1997).

1 Instruction No. 61 Re Commercial Advertisement or Promotion

2 To constitute commercial advertising or promotion, a statement of fact must have
3 been commercial speech, by SIS, for the purpose of influencing consumers to buy SIS's goods or
4 services.⁹⁶ While the statement need not be made in a classic advertising campaign, but may
5 consist instead of more informal types of promotion, the statement must have been disseminated
6 sufficiently to the potential customers to constitute advertising or promotion within that
7 industry.⁹⁷

8 If you find that Intuitive has proved that SIS's false or misleading statements were
9 made in a commercial advertisement or promotion, then you must assess the other elements of
10 Intuitive's false advertising claim. If you find that Intuitive has not proved that SIS's false or
11 misleading statements were made in a commercial advertisement or promotion, then you must
12 find for SIS on Intuitive's false advertising claim.

13
14
15
16
17
18
19
20
21
22
23
24
25
26
27 ⁹⁶ *Newcal Indus., Inc. v. Ikon Office Solution*, 513 F.3d 1038, 1054 (9th Cir. 2008) (citing
28 *Coastal Abstract Service, Inc. v. First Am. Title Ins. Co.*, 173 F.3d 725, 735 (9th Cir. 1999)).
⁹⁷ *Newcal Indus., Inc. v. Ikon Office Solution*, 513 F.3d 1038, 1054 (9th Cir. 2008) (citing
Coastal Abstract Service, Inc. v. First Am. Title Ins. Co., 173 F.3d 725, 735 (9th Cir. 1999)).

1 Instruction No. 62 Re Lanham Act Injury

2 Intuitive must prove by a preponderance of the evidence that it has suffered injury
 3 to a commercial interest in sales or business reputation as a result of SIS's statement, either by a
 4 direct loss of sales or a lessening of the goodwill associated with its products.⁹⁸ This can be
 5 proved in a number of ways. For example, injury can be proved by showing that SIS having
 6 made false statements induced customers to switch their purchasing decisions, and purchase
 7 replacement or repaired EndoWrists from SIS instead of from Intuitive.⁹⁹ Injury could also be
 8 proved by showing that SIS cast aspersions on Intuitive's business or damaged Intuitive's
 9 products' reputation.¹⁰⁰ Injury could also be proved if SIS's false or misleading statements
 10 reduced Intuitive's business by causing customers to demand fewer EndoWrists.¹⁰¹

11 If you find that Intuitive has proved that SIS's false or misleading statements
 12 caused injury to Intuitive, then you should assess the other elements of Intuitive's false
 13 advertising claim. If you find that Intuitive has not proved that SIS's false or misleading
 14 statements caused injury to Intuitive, then you must find for SIS on Intuitive's false advertising
 15 claim.

23 _____
 24 ⁹⁸ *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1136 (9th Cir. 1997); *Newcal Indus.*,
 25 *Inc. v. Ikon Office Solution*, 513 F.3d 1038, 1052 (9th Cir. 2008); FED. CIVIL JURY INSTRUCTIONS
 26 OF THE SEVENTH CIRCUIT § 13.3.1 (Committee on Pattern Civil Jury Instructions 7th Cir. 2017
 27 ed.); PATTERN JURY INSTRUCTIONS OF THE ELEVENTH CIRCUIT § 10.8 (Committee on Pattern Jury
 Instructions 11th Cir. 2024 ed.); MANUAL OF MODEL CIVIL JURY INSTRUCTIONS FOR THE
 DISTRICT COURTS OF THE EIGHTH CIRCUIT § 21.43 (Committee on Model Jury Instructions 8th
 Cir. 2023 ed.).

28 ⁹⁹ *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 137–40 (2014).

¹⁰⁰ *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 137–40 (2014).

¹⁰¹ *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 137–40 (2014).

1 Instruction No. 63 Re Willfulness for False Advertising

2 If you have determined that SIS engaged in false advertising, you must also
3 determine whether such conduct was willful on the part of SIS. SIS's actions may be considered
4 willful if SIS knew that it was engaging in false advertising, or if it acted with indifference to
5 Intuitive's rights.¹⁰²

28 _____
¹⁰² *Romag Fasteners, Inc. v. Fossil, Inc.*, 590 U.S. 212, 219 (2020).

B. Common Law Unfair Competition

Instruction No. 64 Re Common Law Unfair Competition

Intuitive claims that SIS's conduct constitutes unfair competition under California's common law. The essence of the tort of unfair competition is the inequitable pirating of the fruits of another's labor and then either "palming off" those fruits as one's own through deception, or simply gaming from them an unearned commercial benefit.¹⁰³

To prevail on this claim, Intuitive must prove that:

1. SIS subjectively and knowingly intended to confuse buyers of EndoWrists by passing off its products in such manner as to induce those customers to believe that SIS's repaired EndoWrists were identical to original EndoWrists sold by Intuitive;
2. Customers for EndoWrists were likely to be confused, meaning they were misled into thinking that SIS's repaired EndoWrists were actually identical to original EndoWrists sold by Intuitive; and
3. SIS thereby caused Intuitive a competitive injury, meaning that Intuitive must have suffered some actual economic harm to its business that was caused by SIS's deception of Intuitive's actual and potential customers.¹⁰⁴

If you find that Intuitive has proved each of these elements by a preponderance of the evidence, then you must find for Intuitive and against SIS on Intuitive's common law unfair competition claim. If you find that Intuitive has not proved each of these elements by a preponderance of the evidence, then you must find for SIS and against Intuitive on Intuitive's common law unfair competition claim.

¹⁰³ *Rider Clothing LLC v. Boardriders, Inc.*, 2019 WL 8163813, at *5 (C.D. Cal. Nov. 26, 2019).
¹⁰⁴ *Rider Clothing LLC v. Boardriders, Inc.*, 2020 WL 4578700, at *3 (C.D. Cal. Aug. 7, 2020); *Fisher v. Dees*, 794 F.2d 432, 440 (9th Cir. 1986); *TMC Aerospace, Inc. v. Elbit Sys. of Am. LLC*, 2016 WL 3475322, at *8 (C.D. Cal. Jan. 29, 2016).

C. Intentional Interference with Contractual Relations

Instruction No. 65 Re Tortious Interference with Contract¹⁰⁵

Intuitive claims that SIS intentionally interfered with the contracts between it and certain customers. To establish this claim, Intuitive must prove all of the following:

- (1) That there was a contract between Intuitive and each of its customers at issue;
- (2) That SIS knew of such contracts;
- (3) That SIS's conduct prevented performance of the contract by Intuitive or made performance more expensive or difficult;
- (4) That SIS intended to disrupt the performance of the contracts between Intuitive and its customers, or knew that disruption of performance was certain or substantially certain to occur;
- (5) That Intuitive was harmed; and
- (6) That SIS's conduct was a substantial factor in causing Intuitive's harm.

If you find that Intuitive has proved each of these elements by a preponderance of the evidence, then you must find for Intuitive and against SIS on Intuitive's tortious interference with contract claim. If you find that Intuitive has not proved each of these elements by a preponderance of the evidence, then you must find for SIS and against Intuitive on Intuitive's tortious interference with contract claim.

¹⁰⁵ Judicial Council of California Civil Jury Instructions 2201 – Intentional Interference with Contractual Relations – Essential Factual Elements (2024 ed.); *Pacific Gas & Electric Co. v. BearStearns & Co.*, 50 Cal.3d 1118, 1126 (1990).

D. Damages on Intuitive's Counterclaims

Instruction No. 66 Re Lost Profit Damages on Intuitive Counterclaims

If you decide for Intuitive on the question of liability on its counterclaims, then you should consider the amount of money to award to Intuitive as damages. This should include damages that Intuitive sustained, and profits that SIS made, because of SIS's conduct.¹⁰⁶ By instructing you on damages, the Court does not mean to suggest for which party your verdict should be rendered.

Damages consist of the amount of money required to compensate Intuitive for the injury caused by SIS's conduct.¹⁰⁷ Plaintiff must prove its damages by a preponderance of the evidence.¹⁰⁸

For the claims of unfair competition, false advertising, or tortious interference with contracts, Intuitive asks to be awarded lost profit damages. That is, Intuitive asks to be awarded the lost profits that it would have earned but for SIS's unfair competition, false advertising, or tortious interference with contracts.

To decide the amount of damages for lost profits, you must determine the gross amount Intuitive would have received but for SIS's conduct and then subtract from that amount the expenses Intuitive would have had if SIS's conduct had not occurred.¹⁰⁹ The amount of the lost profits need not be calculated with mathematical precision, but there must be a reasonable basis for computing the loss.¹¹⁰

¹⁰⁶ FED. CIVIL JURY INSTRUCTIONS OF THE SEVENTH CIRCUIT § 13.6.1 (Committee on Pattern Civil Jury Instructions 7th Cir. 2017 ed.).

¹⁰⁷ FED. CIVIL JURY INSTRUCTIONS OF THE SEVENTH CIRCUIT § 13.6.3 (Committee on Pattern Civil Jury Instructions 7th Cir. 2017 ed.).

¹⁰⁸ FED. CIVIL JURY INSTRUCTIONS OF THE SEVENTH CIRCUIT § 13.6.3 (Committee on Pattern Civil Jury Instructions 7th Cir. 2017 ed.).

¹⁰⁹ Judicial Council of California Civil Jury Instructions 3903N – Lost Profits (2024 ed.); *see also* FED. CIVIL JURY INSTRUCTIONS OF THE SEVENTH CIRCUIT § 13.6.3 (Committee on Pattern Civil Jury Instructions 7th Cir. 2017 ed.) (“You may consider the following types of damages: Plaintiff's lost profits on lost sales, which consists of the revenue Plaintiff would have earned but for Defendant's infringement, less the expenses Plaintiff would have sustained in earning those revenues.”).

¹¹⁰ Judicial Council of California Civil Jury Instructions 3903N – Lost Profits (2024 ed.).

Dated: September 25, 2024

By: /s/ **DRAFT**

Kenneth A. Gallo

Kenneth A. Gallo (*pro hac vice*)
Paul D. Brachman (*pro hac vice*)
**PAUL, WEISS, RIFKIND, WHARTON &
GARRISON LLP**
2001 K Street, NW
Washington, DC 20006-1047
Telephone: (202) 223-7300
Facsimile: (202) 204-7420
Email: kgallo@paulweiss.com
Email: pbrachman@paulweiss.com

William B. Michael (*pro hac vice*)
Crystal L. Parker (*pro hac vice*)
Daniel A. Crane (*pro hac vice*)
**PAUL, WEISS, RIFKIND, WHARTON &
GARRISON LLP**
1285 Avenue of the Americas
New York, NY 10019-6064
Telephone: (212) 373-3000
Facsimile: (212) 757-3990
Email: wmichael@paulweiss.com
Email: cparker@paulweiss.com
Email: dcrane@paulweiss.com

Joshua Hill Jr. (SBN 250842)
**PAUL, WEISS, RIFKIND, WHARTON &
GARRISON LLP**
535 Mission Street, 24th Floor
San Francisco, CA 94105
Telephone: (628) 432-5100
Facsimile: (628) 232-3101
Email: jhill@paulweiss.com

Sonya D. Winner (SBN 200348)
COVINGTON & BURLINGTON LLP
415 Mission Street, Suite 5400
San Francisco, California 94105-2533
Telephone: (415) 591-6000
Facsimile: (415) 591-6091
Email: swinner@cov.com

Kathryn E. Cahoy (SBN 298777)

1 **COVINGTON & BURLINGTON LLP**
2 3000 El Camino Real
3 5 Palo Alto Square, 10th Floor
4 Palo Alto, California 94306-2112
5 Telephone: (650) 632-4700
6 Facsimile: (650) 632-4800
7 Email: kcahoy@cov.com

8 Andrew Lazerow (*pro hac vice*)
9 **COVINGTON & BURLINGTON LLP**
10 One City Center 850 Tenth Street NW
11 Washington DC 20001-4956
12 Telephone: (202) 662-6000
13 Facsimile: (202) 662-6291
14 Email: alazerow@cov.com

15 Allen Ruby (SBN 47109)
16 **ALLEN RUBY, ATTORNEY AT LAW**
17 15559 Union Ave. #138
18 Los Gatos, California 95032
19 Telephone: (408) 477-9690
20 Email: allen@allenruby.com

21 *Attorneys for Defendant*
22 *Intuitive Surgical, Inc.*
23
24
25
26
27
28

Exhibit 6

EXHIBIT 6 -- PROPOSED LIMITING / CAUTIONARY JURY INSTRUCTION

You may hear testimony and see documents related to obtaining FDA clearance to market certain EndoWrist instruments. Such testimony and related documents have very limited relevance to the issues of this case. The Court previously ruled that the FDA has not determined whether 510(k) clearance is necessary for SIS's EndoWrist services. Additionally, the Court previously ruled that it is the Federal Government, rather than private litigants, who are authorized to file suit for noncompliance with the medical device provisions. Intuitive, as a private party, has no authority to enforce the Food, Drug, and Cosmetic Act or its implementing regulations in this case. You should not consider whether or not Intuitive received FDA clearance for the da Vinci robot or EndoWrists for any reason in this trial. Instead, for purposes of this trial, you must assume that FDA clearance is entirely immaterial as to whether Intuitive's use limits were proper or whether Intuitive's actions to enforce those use limits were proper.

Kenneth A. Gallo (*pro hac vice*)
Paul D. Brachman (*pro hac vice*)
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
2001 K Street, NW
Washington, DC 20006-1047
Telephone: (202) 223-7300
Facsimile: (202) 204-7420
Email: kgallo@paulweiss.com
Email: pbrachman@paulweiss.com

William B. Michael (*pro hac vice*)
Crystal L. Parker (*pro hac vice*)
Daniel A. Crane (*pro hac vice*)
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019-6064
Telephone: (212) 373-3000
Facsimile: (212) 757-3990
Email: wmichael@paulweiss.com
Email: cparker@paulweiss.com
Email: dcrane@paulweiss.com

Joshua Hill Jr. (SBN 250842)
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
535 Mission Street, 24th Floor
San Francisco, CA 94105
Telephone: (628) 432-5100
Facsimile: (628) 232-3101
Email: jhill@paulweiss.com

Attorneys for Defendant Intuitive Surgical, Inc.

[Additional counsel listed on signature page]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

SURGICAL INSTRUMENT SERVICE
COMPANY, INC.,

Plaintiff,

v.

INTUITIVE SURGICAL, INC.,

Defendant.

Case No. 3:21-cv-03496-AMO

**DEFENDANT INTUITIVE SURGICAL
INC.'S OPPOSITION TO PLAINTIFF
SURGICAL INSTRUMENT SERVICE,
INC.'S MOTION *IN LIMINE* #5**

Date: November 25, 2024

Time: 11:00 a.m.

Courtroom: 10

The Honorable Araceli Martínez-Olguín

SIS's motions *in limine* ("MILs") Nos. 1 and 5 effectively ask the Court to exclude any mention of the FDA from the upcoming trial.¹ SIS bases its arguments entirely on the Court's order denying Intuitive's motion for summary judgment. Mot. at 1–2. As a result, all of the reasons presented in Intuitive's opposition to MIL No. 1 apply equally to MIL No. 5. The Court should deny MIL No. 5 based on the arguments in Intuitive's opposition to MIL No. 1 (which is incorporated here by reference) as well as for the additional reasons set forth herein.

I. EVIDENCE RELATING TO 510(K) CLEARANCES FOR ENDOWRISTS IS RELEVANT TO SIS'S ANTITRUST CLAIMS.

The relevance arguments in Intuitive's opposition to SIS's MIL No. 1 apply equally to evidence relating to 510(k) clearances for EndoWrists by Intuitive and Iconocare. The facts of those clearances, and SIS's lack of 510(k) clearance, are relevant to a number of disputed issues on SIS's antitrust claims—including the competitive effects analysis required under the rule of reason, causation, and damages. *See* Opp. MIL No. 1 at 2–5.² Nothing in SIS's one page of argument about the evidence it challenges in MIL No. 5, Mot. at 5, changes that.

First, SIS's attack on *all* FDA-related evidence about usage limits, *id.*, is unavailing. SIS did not move for summary judgment on any aspect of its antitrust claims, and the Court did not grant SIS summary judgment on whether Intuitive's usage limits and related policies have procompetitive justifications. Rather, the Court unequivocally left that issue for the jury:

Intuitive claims that its conduct related to the EndoWrist market has certain benefits, including ensuring product reliability and minimizing risks to patients.

¹ SIS's two motions *in limine* totaling 13 pages on the topic of FDA-related evidence violated the Court's Pretrial Order permitting one motion of up to seven pages on "a single, separate topic." *See* Dkt. 235 at 3, § II.B. The Court should deny MIL Nos. 1 and 5 on this ground alone. *See* Fed. R. Civ. P. 16(f)(1)(C).

² FDA-related evidence is relevant to other issues. For example, the FDA's policies regarding cybersecurity and data security are relevant to explain why Intuitive changed the encryption technology on X/Xi EndoWrists and thus is part of Intuitive's defense to the claim that this change in technology was itself anticompetitive. *See* Dkt. 1 ¶ 107 (alleging that "Intuitive's sole purpose" in changing the encryption technology "is to prevent competition in repair services and to unjustifiably protect its supra-competitive EndoWrist profits"); *Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp. LP*, 592 F.3d 991, 1000 (9th Cir. 2010) ("There is no violation of Section 2 unless plaintiff proves that some conduct of the monopolist associated with its introduction of a new and improved product design 'constitutes an anticompetitive abuse or leverage of monopoly power, or a predatory or exclusionary means of attempting to monopolize the relevant market.'" (citation omitted)).

1 Although patient safety appears to be an important rationale for the manufacture of
 2 surgical robots, SIS argues that such justification amounts to mere pretext. Indeed,
 3 SIS proffers conflicting evidence regarding the patient safety justifications for
 Intuitive's use limits. The directly conflicting evidence regarding the potential
 benefits of Intuitive's conduct is best left for a jury to weigh.

4 Dkt. 204 at 18 (citations omitted). Allowing SIS to challenge this Court's ruling now through a
 5 motion *in limine* would be improper and prejudice Intuitive. *See, e.g., Pavo Sols. LLC v. Kingston*
 6 *Tech. Co.*, 2020 WL 1049911, at *1 (C.D. Cal. Feb. 18, 2020) ("allowing a party to litigate matters"
 7 in a motion *in limine* "that have been or should have been resolved at an earlier stage not only
 8 allows those dissatisfied with the court's initial ruling a chance to relitigate, but also deprives their
 9 opponents of those crucial procedural protections that attach at summary judgment" (cleaned up)).

10 *Second*, SIS's reliance on product liability cases excluding evidence of 510(k) clearance
 11 under Rule 403, Mot. at 5, is entirely misplaced. As an initial matter, those are all cases in which
 12 a party was contesting whether, or to what extent, a clearance determination by the FDA actually
 13 involved a determination of safety and effectiveness. Here, that issue is not in dispute. Everyone
 14 agrees that the FDA determined Intuitive's EndoWrists to be as safe and effective as the predicate
 15 devices identified. If the FDA had not made that determination, SIS would have had **no** basis to
 16 tell customers that it could "extend the[] **safe and effective** life" of EndoWrists by resetting the
 17 use counter. *See, e.g., Ex. 1* at -127 (emphasis added).³ Everyone also agrees that the FDA
 18 determined Iconocare's modified EndoWrist to be as safe and effective as Intuitive's EndoWrists.
 19 *Ex. 2* ¶¶ 120–21; *Ex. 3* ¶¶ 129–30. And it is undisputed that the FDA made **no** such determination
 20 of safety and effectiveness as to EndoWrists modified by Rebotix and re-sold by SIS. The cases
 21 that SIS cites do not remotely support an argument that these facts—all of which SIS itself has put
 22 at issue, *see Opp. to MIL No. 1* at 2–4—are not relevant or probative in the context of SIS's
 23 antitrust claims, or that it would be unfairly prejudicial for the jury to hear them.

24 SIS's reading of *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), Mot. at 5, misses the mark.
 25 The Supreme Court acknowledged in that case that "the FDA may well examine § 510(k)
 26 applications . . . with a concern for the safety and effectiveness of the device," *Medtronic*, 518
 27

28 ³ "Ex." refers to the exhibits to the Declaration of Andrew Lazerow in Support of Intuitive
 Surgical Inc.'s Opposition to SIS's Motion *in Limine* #5.

1 U.S. at 493, and has since clarified that “the FDA simultaneously maintains the exhaustive PMA
 2 and the more limited § 510(k) processes *in order to ensure . . . that medical devices are reasonably*
 3 *safe and effective*,” *Buckman v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 349–50 (2001) (emphasis
 4 added). And more recently, one court in this circuit explained that the Supreme Court in *Medtronic*
 5 “did **not** find that [510(k) clearance] has no bearing on a device’s safety and effectiveness.” *Otero*
 6 *v. Zeltiq Aesthetics, Inc.*, 2018 WL 3012942, at *3 (C.D. Cal. June 11, 2018) (emphasis added).
 7 Thus, SIS “ignores the significance of the FDA’s decision” to classify a device as Class II, which
 8 indicates that “certain ‘special controls’ provide ‘reasonable assurance of the safety and
 9 effectiveness of the device.’” *Id.* (citations omitted). “It follows that” Intuitive’s argument that
 10 the FDA determined that its instruments are safe and effective “is not a claim that can only be
 11 made if the procedure was FDA approved and not FDA Cleared.” *Id.* (cleaned up).

12 Further, in contrast to cases SIS cites, Mot. at 5, this is not a case where there are reasons
 13 to doubt the rigor of a particular 510(k) or where the clearance itself has “several red flags” such
 14 that it is not probative of actual safety. *See, e.g., Kaiser v. Johnson & Johnson*, 947 F.3d 996,
 15 1018 (7th Cir. 2020). Rather, the facts here demonstrate that safety and effectiveness was central
 16 to the 510(k) process for EndoWrists. For example, the FDA issued a deficiency letter to Rebotix
 17 that identified over 50 deficiencies in its 510(k) submission for modified EndoWrists in 2015 (the
 18 same instruments SIS offered to hospitals). Ex. 4. The FDA requested, among other items,
 19 additional information “necessary to establish substantial equivalence, *in terms of safety*, to the
 20 predicate device.” *Id.* at 21 (emphasis added). The FDA asked Rebotix to repeat its “*safety testing*
 21 on end-of life devices,” *id.* at 23 (emphasis added), and raised concerns about sterilization of
 22 patient-contacting parts of the devices, *id.* at 3, 11, 14–15, 21–22.

1 [REDACTED]
2 [REDACTED]
3 FDA's concern with safety and effectiveness around extending the number of uses of
4 EndoWrists also permeated other FDA communications that SIS seeks to exclude. Mot. at 1–2.
5 For example, when Rebotix engaged with the FDA in 2022 about the regulatory status of modified
6 EndoWrists, FDA's team lead focused on safety and effectiveness as the basis for FDA's view
7 "that the activities of Rebotix constitute remanufacturing and would require FDA review and
8 clearance (e.g. 510(k) / de Novo)," and for FDA's resulting request that "Rebotix stop engaging
9 in the current activities until an application is reviewed and cleared/granted":

10 ***The instruments in question no longer maintain the same safety and effectiveness***
11 ***profile as cleared with the original manufacturer's own submission.*** During
12 premarket review, FDA reviews test data to the labeled number of reuse cycles.
13 This includes, but is not limited to, items such as electrical safety, reprocessing,
14 software, and general performance testing. By extending the number of uses and
15 modifying the instrument with a new chip, ***the prior information is no longer valid***
16 ***and requires additional review to the new labeled usage limit in order to establish***
17 ***safety and effectiveness.***

18 Ex. 7 at -727 (emphasis added).

19 *Third*, the product liability cases on which SIS relies, Mot. at 5, are also of no use here
20 because evidence of 510(k) clearance was tangential (at best) to the product liability issues in those
21 cases, whereas such evidence is centrally relevant to SIS's antitrust claims. *See Carter v. Johnson*
22 *& Johnson*, 2022 WL 4700549, at *1 (D. Nev. Sept. 29, 2022) (citing Mem. Op. & Order at 7,
23 *Carter v. Johnson & Johnson*, No. 2:20-cv-01232 (D. Nev. June 28, 2020), Dkt. 148-11 (finding
24 that opinions about the 510(k) regulatory framework were "not helpful to the jury in determining
25 the facts at issue in these cases")); *cf.* Dkt. 203 at 20 ("Phillips's knowledge and experience with
26 the regulatory framework, however, will 'help the trier of fact to understand the evidence or to
27 determine a fact in issue[.]'" (citation omitted)). Whether an injured patient plaintiff in a product
28 liability case could prove that the device was defective is a starkly different inquiry than whether,
for example, it was reasonable under the antitrust laws for Intuitive to require that third-party
products and services used with its systems be authorized—and to rely on 510(k) clearance as an
indicator of safety and effectiveness where a third party declined to present clinical evidence of

1 safety directly to Intuitive. The issues here are about the competitive impact of 510(k) clearance,
 2 not whether Intuitive’s designs meet a reasonable design standard under state tort laws. *See*
 3 *Campbell v. Bos. Sci. Corp.*, 2016 WL 5796906, at * 15 (S.D.W. Va. Oct. 3, 2016) (“Jurors are
 4 likely to believe that FDA enforcement relates to the validity of the plaintiffs’ state law tort claims,
 5 which it does not. . . . [A]lleged shortcomings in FDA procedures are not probative to a state law
 6 products liability claim.” (citation omitted)).

7 *Finally, Enborg v. Ethicon, Inc.*, 2022 WL 850762 (E.D. Cal. Mar. 22, 2022), on which
 8 SIS relies, Mot. at 5, is inapposite. Whether the 510(k) process requires device producers to “meet
 9 any established design standards,” *id.* at 5, is not the issue here. Instead, the question is whether
 10 the 510(k) process requires manufacturers to make a showing to the FDA sufficient to ensure the
 11 safety and efficacy of its devices. The answer to that question is unquestionably yes for the reasons
 12 shown above. SIS’s own FDA expert acknowledges, for example: “The objective of FDA device
 13 regulation is to provide the American public with reasonable assurance of the safety and
 14 effectiveness for all medical devices[.]” Ex. 2 ¶ 20; *see id.* ¶ 24 (“FDA regulation of devices
 15 provides a ‘reasonable assurance of safety and effectiveness.’”).

16 **II. FDA-RELATED EVIDENCE IS RELEVANT TO THE CREDIBILITY OF SIS’S** 17 **WITNESSES.**

18 FDA-related evidence is also relevant to the jury’s determination of the credibility of SIS’s
 19 witnesses. *See, e.g., Henderson v. George Washington Univ.*, 449 F.3d 127, 139 (D.C. Cir. 2006)
 20 (Rule 403 did not justify exclusion of evidence that had probative value both as “affirmative
 21 evidence” and “for purposes of impeachment, rebuttal, and rehabilitation.”). SIS’s executives,
 22 Greg Posdal and Keith Johnson, both testified that they knew that Rebotix had applied for FDA
 23 clearance but did not know whether Rebotix had been granted clearance. Ex. 8 at 54:23–54:7; Ex.
 24 9 at 65:10–16, 66:2–6. Indeed, both of them claim to know nothing about the information in
 25 Rebotix’s application or the FDA’s response in its extensive deficiency letter to Rebotix, even
 26 though they repeatedly told customers the device had been proven safe. *See* Ex. 9 at 66:7–23; Ex.
 27 8 at 55:8–19; Ex. 10 at 49:23–50:1. Intuitive is entitled to a thorough cross-examination of SIS’s
 28 trial witnesses, including on this topic that goes to their credibility. *See, e.g., Palantir Techs. Inc.*

1 *v. Abramowitz*, 639 F. Supp. 3d 981, 986–87 (N.D. Cal. 2022) (denying motion *in limine* to exclude
 2 evidence that implicated the credibility of the plaintiff company’s officer because the relevance of
 3 the “critical” witness’s credibility was not substantially outweighed by the Rule 403 dangers).

4 **III. SIS CANNOT MEET THE HIGH BAR FOR EXCLUSION UNDER RULE 403.**

5 Rule 403 sets a “high bar” for exclusion, *Sidibe v. Sutter Health*, 103 F.4th 675, 691 (9th
 6 Cir. 2024), which SIS cannot satisfy. Excising all references to FDA clearance from the trial
 7 would create a false and misleading evidentiary record and prejudice Intuitive. *See Armor Corr.*
 8 *Health Servs., Inc. v. Teal*, 2022 WL 18458135, at *5–6 (S.D. Fla. Jan. 7, 2022) (denying motion
 9 *in limine* to exclude evidence that defendant “[wa]s entitled to present” where plaintiff did not
 10 “demonstrate[] that this evidence is clearly inadmissible”). And SIS cannot show this is evidence
 11 “of scant or cumulative probative force, dragged in by the heels for the sake of its prejudicial
 12 effect.” *United States v. Haischer*, 780 F.3d 1277, 1282 (9th Cir. 2015) (citation omitted).

13 SIS argues that introduction of FDA clearance evidence would present a risk of “undue
 14 deference to a federal agency,” Mot. at 5, but it neither articulates any specific reasons establishing
 15 such a risk nor shows that the risk substantially outweighs the probative value of the evidence. *See*
 16 *Munoz v. PHH Mortg. Corp.*, 2022 WL 138670, at *2 (E.D. Cal. Jan. 14, 2022) (denying motion
 17 *in limine* because “the party invoking Rule 403 has to carry a ‘significant burden’” and the moving
 18 party failed to offer “specific reasons why the jury will be confused” (citation omitted)). In
 19 *Tenorio v. Pitzer*, the district court considered a motion to exclude an opinion letter from the DOJ
 20 on the grounds that “the jury would give undue deference to the opinion of the DOJ and substitute
 21 the DOJ’s conclusions for its own judgment.” 2019 WL 687853, at *10 (D.N.M. Feb. 19, 2019).
 22 The court denied the motion, holding that the letter was “highly probative of the issues” and “its
 23 probative value is not outweighed by the danger of prejudice, confusion of the issues, or misleading
 24 the jury.” *Id.* at *12; *see also id.* (“Defendants’ arguments concerning errors, conflicting
 25 statements, and omissions in the report are issues ripe for cross examination and go to the weight
 26 the jury should give the evidence . . .”); *Tijerina v. Alaska Airlines, Inc.*, 2024 WL 2097902, at *7
 27 (S.D. Cal. May 9, 2024) (denying motion *in limine* to exclude EEOC records where the moving
 28 party failed to show that the evidence “will likely confuse the jury, who will misunderstand the

1 EEOC’s role and give the EEOC’s work product undue deference”). SIS fails to explain how the
2 risk of juror confusion (if any) would outweigh the probative value of evidence about FDA
3 clearance in a case about medical devices and safety. Indeed, this is just another example of how
4 SIS is trying to distort the record by hiding clearly relevant and probative evidence from the jury.
5 In the real world, FDA clearance *is* recognized as a marker of quality and reliability by hospitals,
6 and thus has an effect on demand for medical devices, as the record in this case establishes. *See*
7 *Opp. to MIL No. 1 at 5*. That is part of what makes the evidence relevant—not unduly prejudicial.

8 Even so, Intuitive is not asking the jury to defer to the FDA; rather, the evidence will allow
9 the jury to understand the history of the usage limits and contractual restrictions and Intuitive’s
10 intent in implementing them. “There is nothing unfair about admitting evidence of precisely that.”
11 *Sidibe*, 103 F.4th at 702; *see also id.* (“The history of a restraint and the reasons for adopting it are
12 essential aspects of the rule of reason analysis . . .”). Additionally, the jury could consider the
13 evidence that Rebotix used a reset process that the FDA found to be deficient and determine that
14 SIS’s inattentiveness to these deficiencies, and resulting inability to address customer concerns
15 about safety, caused its injury, not Intuitive’s conduct. *See Opp. to MIL No. 1 at 5*.

16 SIS relies on FDA regulations to show that its modified EndoWrists—which are not cleared
17 by FDA and did not meet FDA standards for clearance—are safe. At the same time, SIS argues
18 that Intuitive cannot present evidence that its devices—which *are* reviewed and cleared by FDA,
19 in carrying out its charge to “ensure . . . that medical devices are reasonably safe and effective,”
20 *Buckman*, 531 U.S. at 349–50—have a reasonable assurance of safety. SIS cannot have it both
21 ways. *See, e.g., In re HHE Choices Health Plan, LLC*, 2019 WL 6112679, at *12 (Bankr. S.D.N.Y.
22 Nov. 15, 2019) (“[Plaintiff] would like to tell a one-sided story in which he is free to tell the jury
23 about the Defendants’ negative dealings with regulators, but in which any other dealings with
24 regulators and evidence of regulatory compliance are off-limits. That is not appropriate.”).

25 CONCLUSION

26 For the foregoing reasons and those in Intuitive’s Opposition to MIL No. 1, the Court
27 should deny SIS’s MIL No. 5.

1 Dated: November 7, 2024

By: /s/ Kenneth A. Gallo

Kenneth A. Gallo

2
3 Kenneth A. Gallo (*pro hac vice*)
4 Paul D. Brachman (*pro hac vice*)
5 **PAUL, WEISS, RIFKIND, WHARTON &**
6 **GARRISON LLP**
7 2001 K Street, NW
8 Washington, DC 20006-1047
Telephone: (202) 223-7300
Facsimile: (202) 204-7420
Email: kgallo@paulweiss.com
Email: pbrachman@paulweiss.com

9 William B. Michael (*pro hac vice*)
10 Crystal L. Parker (*pro hac vice*)
11 Daniel A. Crane (*pro hac vice*)
12 **PAUL, WEISS, RIFKIND, WHARTON &**
13 **GARRISON LLP**
14 1285 Avenue of the Americas
15 New York, NY 10019-6064
16 Telephone: (212) 373-3000
17 Facsimile: (212) 757-3990
18 Email: wmichael@paulweiss.com
19 Email: cparker@paulweiss.com
20 Email: dcrane@paulweiss.com

21 Joshua Hill Jr. (SBN 250842)
22 **PAUL, WEISS, RIFKIND, WHARTON &**
23 **GARRISON LLP**
24 535 Mission Street, 24th Floor
25 San Francisco, CA 94105
26 Telephone: (628) 432-5100
27 Facsimile: (628) 232-3101
28 Email: jhill@paulweiss.com

Sonya D. Winner (SBN 200348)
COVINGTON & BURLINGTON LLP
415 Mission Street, Suite 5400
San Francisco, California 94105-2533
Telephone: (415) 591-6000
Facsimile: (415) 591-6091
Email: swinner@cov.com

Kathryn E. Cahoy (SBN 298777)
COVINGTON & BURLINGTON LLP
3000 El Camino Real

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

5 Palo Alto Square, 10th Floor
Palo Alto, California 94306-2112
Telephone: (650) 632-4700
Facsimile: (650) 632-4800
Email: kcahoy@cov.com

Andrew Lazerow (*pro hac vice*)
COVINGTON & BURLINGTON LLP
One City Center 850 Tenth Street NW
Washington DC 20001-4956
Telephone: (202) 662-6000
Facsimile: (202) 662-6291
Email: alazerow@cov.com

Allen Ruby (SBN 47109)
ALLEN RUBY, ATTORNEY AT LAW
15559 Union Ave. #138
Los Gatos, California 95032
Telephone: (408) 477-9690
Email: allen@allenruby.com

*Attorneys for Defendant
Intuitive Surgical, Inc.*

CERTIFICATE OF SERVICE

On November 7, 2024, I caused a copy of Intuitive's Opposition to SIS's Motion *In Limine* No. 5 to be served via electronic e-mail on counsel of record for Surgical Instrument Service Company, Inc. pursuant to the Court's Schedule and Pretrial Order in this case, ECF No. 235.

Dated: November 7, 2024

By: /s/ Kenneth A. Gallo

Kenneth A. Gallo

1 Kenneth A. Gallo (*pro hac vice*)
 Paul D. Brachman (*pro hac vice*)
 2 **PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP**
 2001 K Street, NW
 3 Washington, DC 20006-1047
 Telephone: (202) 223-7300
 4 Facsimile: (202) 204-7420
 Email: kgallo@paulweiss.com
 5 Email: pbrachman@paulweiss.com

6 William B. Michael (*pro hac vice*)
 Crystal L. Parker (*pro hac vice*)
 7 Daniel A. Crane (*pro hac vice*)
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
 8 1285 Avenue of the Americas
 New York, NY 10019-6064
 9 Telephone: (212) 373-3000
 Facsimile: (212) 757-3990
 10 Email: wmichael@paulweiss.com
 Email: cparker@paulweiss.com
 11 Email: dcrane@paulweiss.com

12 Joshua Hill Jr. (SBN 250842)
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
 13 535 Mission Street, 24th Floor
 San Francisco, CA 94105
 14 Telephone: (628) 432-5100
 Facsimile: (628) 232-3101
 15 Email: jhill@paulweiss.com

16 *Attorneys for Defendant Intuitive Surgical, Inc.*

17 [Additional counsel listed on signature page]

18 **UNITED STATES DISTRICT COURT**
 19 **FOR THE NORTHERN DISTRICT OF CALIFORNIA**
 20 **SAN FRANCISCO DIVISION**

21 SURGICAL INSTRUMENT SERVICE
 COMPANY, INC.,

22 *Plaintiff,*

23 v.

24 INTUITIVE SURGICAL, INC.,

25 *Defendant.*

Case No.: 3:21-cv-03496-AMO

**DECLARATION OF ANDREW LAZEROW
 IN SUPPORT OF INTUITIVE SURGICAL
 INC.'S OPPOSITION TO SIS'S MOTION IN
 LIMINE #5**

Date: November 25, 2024

Time: 11:00 a.m.

Courtroom: 10

Judge: The Honorable Araceli Martínez-Olguín

1 I, ANDREW LAZEROW, declare as follows:

2 1. I am an attorney licensed to practice in the District of Columbia and Maryland and am
3 admitted to practice *pro hac vice* before this Court. I am a partner with the law firm of Covington &
4 Burling LLP, counsel for Intuitive Surgical, Inc. (“Intuitive”) in this matter. I have personal knowledge
5 of the facts set forth herein, and if called to testify, I could and would testify competently thereto.

6 2. Attached to this declaration as **Exhibit 1** is a true and correct copy of Defendant’s
7 Exhibit 136, a series of emails culminating in a September 25, 2019 email from Keith Johnson to
8 Timothy P. Brooks and Perry Kirwan, attaching marketing materials for SIS’s EndoWrist repair
9 program, produced by Plaintiff Surgical Instrument Services Company, Inc. (“SIS”) as SIS095115 –
10 SIS095139.

11 3. Attached to this declaration as **Exhibit 2** is a true and correct copy of excerpts of the
12 Expert Report of Philip J. Phillips that SIS served in this litigation on December 2, 2022.

13 4. Attached to this declaration as **Exhibit 3** is a true and correct copy of excerpts of the
14 Expert Report of Dr. Russell Lamb that SIS served in this litigation on December 2, 2022.

15 5. Attached to this declaration as **Exhibit 4** is a true and correct copy of Defendant’s
16 Exhibit 256, a letter from FDA to Rebotix LLC on June 23, 2015, produced by third party Rebotix
17 Repair LLC as REBOTIX171030 – REBOTIX171057.

18 6. Attached to this declaration as **Exhibit 5** is a true and correct copy of Defendant’s
19 Exhibit 266, a letter from FDA to Iconocare Health on March 30, 2021, produced by third party Alliance
20 Healthcare Partners as AHP000527 – AHP000537.

21 7. Attached to this declaration as **Exhibit 6** is a true and correct copy of the summary of the
22 510(k) clearance for the 8mm Monopolar Curved Scissors device remanufactured by Iconocare Health,
23 downloaded on November 4, 2024 from the FDA’s website at
24 https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210478.pdf.

25 8. Attached to this declaration as **Exhibit 7** is a true and correct copy of Defendant’s
26 Exhibit 267, a series of email communications culminating in a May 25, 2022 email from Glen Papit to
27
28

1 Ken Skodacek and Chris Gibson, produced by third party Rebotix Repair LLC as REBOTIX175710 –
2 REBOTIX175730.

3 9. Attached to this declaration as **Exhibit 8** is a true and correct copy of excerpts of the
4 transcript of the deposition of Greg Posdal taken in this litigation on November 1, 2022.

5 10. Attached to this declaration as **Exhibit 9** is a true and correct copy of excerpts of the
6 transcript of the deposition of Keith Johnson, 30(b)(6) representative for SIS, taken in this litigation on
7 October 27, 2022.

8 11. Attached to this declaration as **Exhibit 10** is a true and correct copy of excerpts of the
9 transcript of the deposition of Greg Posdal, 30(b)(6) representative for SIS, taken in this litigation on
10 November 1, 2022.

11 I declare under the laws of the United States that the foregoing is true and correct.

12
13
14 DATED: November 7, 2024

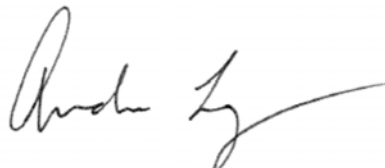
15 
16 _____
17 ANDREW LAZEROW
18
19
20
21
22
23
24
25
26
27
28

EXHIBIT 1
to
DECLARATION OF ANDREW LAZEROW IN SUPPORT OF
INTUITIVE SURGICAL INC.'S OPPOSITION TO SIS'S
MOTION IN LIMINE #5

Message

From: Keith Johnson [krjohnson@sis-usa.com]
Sent: 9/25/2019 7:47:21 PM
To: Brooks, Timothy P. [Timothy.Brooks@bannerhealth.com]; Kirwan, Perry [Perry.Kirwan@bannerhealth.com]
Subject: Re: UMC Tucson
Attachments: da Vinci EndoWrist Repair_2019 copy.pdf; da Vinci EndoWrist Process_2019.pdf; SIS Summary of Quality Regulatory.pdf; EndoWrist FAQs.pdf

Hi Tim, I have attached the documents we have put together to support this program.

Please let me know if this helps, if we need to create any new documents, let's do it. I will need to have our corporate compliance and legal sign off on it prior to publication.

Excited to work on this project with you.

Keith

Keith Johnson | EVP, Sales and Clinical Programs
Surgical Instrument Service Co., Inc.
 Corp: 800.747.8044 | Cell: 623.687.5056
www.sis-usa.com

From: Brooks, Timothy P. <Timothy.Brooks@bannerhealth.com>
Sent: Wednesday, September 25, 2019 4:20 PM
To: Kirwan, Perry <Perry.Kirwan@bannerhealth.com>; Keith Johnson <krjohnson@sis-usa.com>
Subject: RE: UMC Tucson

Anything you have that I can build a process to a competency to will help.

Tim Brooks, BS, CSPM,
 Director – Banner Health Systems CSPD Program
 Office - 520-694-6106
 Cell – 520-400-6790



SPD exists to make a difference in people's lives through excellent service to our patient care providers!!!
 Be Bold – Be Kind – Be Awesome

From: Kirwan, Perry <Perry.Kirwan@bannerhealth.com>
Sent: Wednesday, September 25, 2019 4:12 PM
To: Keith Johnson <krjohnson@sis-usa.com>; Brooks, Timothy P. <Timothy.Brooks@bannerhealth.com>
Subject: RE: UMC Tucson

Keith – if you have some process docs that we worked on as well – please send those to Tim as well

From: Keith Johnson <krjohnson@sis-usa.com>
Sent: Wednesday, September 25, 2019 3:35 PM
To: Kirwan, Perry <Perry.Kirwan@bannerhealth.com>; Brooks, Timothy P. <Timothy.Brooks@bannerhealth.com>
Subject: [EXTERNAL] Re: UMC Tucson

Hi Tim, great to connect again.

Exhibit
Defs 0136

I have attached the document in word format.

Please take a look and let me know your thoughts and recommended changes.

Looking forward to speaking with you soon.

Keith

Keith Johnson | EVP, Sales and Clinical Programs
Surgical Instrument Service Co., Inc.
Corp: 800.747.8044 | Cell: 623.687.5056
www.sis-usa.com

From: Kirwan, Perry <Perry.Kirwan@bannerhealth.com>
Sent: Wednesday, September 25, 2019 10:42 AM
To: Keith Johnson <krjohnson@sis-usa.com>; Brooks, Timothy P. <Timothy.Brooks@bannerhealth.com>
Subject: FW: UMC Tucson

Morning Keith

I think you two have met before so pass on the introductory formalities

We're looking to gear up for Si program at BUMCT/S. I shared with Tim the documentation that I've been working on with you regarding process/procedure as well as supplementing your FAQs on the program as a whole. Can you reach out directly to Tim and share the docs that you have thus far? Tim has agreed to review, edit and also make additional comments if warranted to these documents. I believe this input will prove to be key to the success at Banner however I also believe it will have utility outside of the Banner system as you look to further market this program nationwide.

Tim and I also discussed putting a competency program together for this which I think is a great idea since it's been recommended in other areas that we do the same for central sterile processing. This would just fall in line with those other recommendations.

I believe that we are very close to actual kick-off which is awesome. I'm looking forward to realizing the gains that we believe that this program is going to provide to both of us.

Thanks much!

Perry

From: Brooks, Timothy P. <Timothy.Brooks@bannerhealth.com>
Sent: Wednesday, September 25, 2019 10:35 AM
To: Kirwan, Perry <Perry.Kirwan@bannerhealth.com>
Subject: RE: UMC Tucson

Sounds good, look forward to speaking to him

From: Kirwan, Perry <Perry.Kirwan@bannerhealth.com>
Sent: Wednesday, September 25, 2019 10:18 AM

To: Brooks, Timothy P. <Timothy.Brooks@bannerhealth.com>

Subject: RE: UMC Tucson

Yes – we have been working on documentation for this. That said, I think a review and any suggested edits from your perspective would be awesome. As you alluded to – we want this to be super crisp and eliminate any variables that we can from the process.

I think you're suggestion of competency requirement is also a good one. Just strengthens the precision of what we're doing.

Ok for me to have Keith Johnson reach out to you directly and he can share where we are so far with our documentation. He will be very receptive to edits and even additional information requirements. This is just as much of a learning experience for them as it is us (on process that is – not the actual service).

Thanks Tim for the valuable input

Perry

From: Brooks, Timothy P. <Timothy.Brooks@bannerhealth.com>

Sent: Wednesday, September 25, 2019 10:13 AM

To: Kirwan, Perry <Perry.Kirwan@bannerhealth.com>

Subject: RE: UMC Tucson

Perfect, sounds doable!

We should put this into a competency format that we can get education signoff from staff in both SPD and PeriOp. I am sure IP would like to see that.

Did SIS provide anything that we could formalize into a one or two page competency? I can create the competency, just need their requirements.

From: Kirwan, Perry <Perry.Kirwan@bannerhealth.com>

Sent: Wednesday, September 25, 2019 10:01 AM

To: Brooks, Timothy P. <Timothy.Brooks@bannerhealth.com>

Subject: RE: UMC Tucson

Not exactly. Once we get down to one (1) use on the instrument and that's key - because we need that last count to pull off all the identifying information that's associated with the arm -, we pull the arm out of service and send it to SIS. SIS will use that last count to read the information off and then they will load a full complement of use back on the counter associated with that instrument.

The process would be something like this. As arms come down to central processing, we would use the SIS provided reader to read the arm. If it has two more uses on it – we would process as normal and put it back into circulation. If it has one use on it – we would clean it and then put it into a receptacle (we already have these) for collection. SIS will collect the instruments in the bins and then reload the counters. If an arm say is rated for 10 uses – we would get 10 new uses once it returns from SIS. If the arm has 15 – then it would come back with 15. It is actually important that we don't receive an instrument back with less or more than the intended design otherwise we get into FDA issues because we would be re-manufacturing the device and we obviously don't want that.

Also important is that is we receive an instrument from the OR with zero uses left – it's important to collect those as well. We simply use them for parts and we get repair credit from SIS. So, we never want to toss any of them away as they are no value to use in landfill.

Does that make sense?

From: Brooks, Timothy P. <Timothy.Brooks@bannerhealth.com>
Sent: Wednesday, September 25, 2019 9:36 AM
To: Kirwan, Perry <Perry.Kirwan@bannerhealth.com>
Subject: RE: UMC Tucson

Hi Perry

So the arm would have to be reset after every use?

If so we will have to discuss who is doing this. My preference would be in SPD.

Nick is on vacation this week returning Tuesday next. I spoke to him before going on PTO, he seemed to believe that it would not be a problem.

Tim

From: Kirwan, Perry <Perry.Kirwan@bannerhealth.com>
Sent: Wednesday, September 25, 2019 9:09 AM
To: Brooks, Timothy P. <Timothy.Brooks@bannerhealth.com>
Subject: FW: UMC Tucson

Morning Tim

We have ordered a device from SIS that will allow us to get a 'count' on the Si Robotic arms without having to connect it to the full robot – should make workflow in central processing (or elsewhere) a little easier in terms of tracking the counters.

I'm wondering if we are at a point where we're ready to conduct our pilot at BUMCT/S.

Let me know your thoughts

Thx
Perry

From: Keith Johnson <krjohnson@sis-usa.com>
Sent: Wednesday, September 25, 2019 6:34 AM
To: Kirwan, Perry <Perry.Kirwan@bannerhealth.com>
Subject: [EXTERNAL] UMC Tucson

Are we good to schedule the install and training on the counter for next Tuesday?

Keith Johnson | Executive Vice President
Sales and Clinical Programs
Surgical Instrument Service Co., Inc.
Corp: [800.747.8044](tel:800.747.8044) | Cell: [623.687.5056](tel:623.687.5056)
www.sis-usa.com



Surgical Instrument Service Co., Inc.

da Vinci® EndoWrist® Repair FAQs

Can you send me your certification / FDA approval?

The FDA does not regulate, nor certify, repairs. The FDA regulates third party reprocessing companies and single-use devices only.

What does your service provide?

SIS's service is a complete repair of the da Vinci® EndoWrist® instruments. The instruments are sold with a use counter which limits the life of the instrument. Upon reaching a zero count the instruments are "expired" and rendered useless.

This service includes resetting the use counter via a replacement chip as well as a complete evaluation and repair of the distal/tool end of the instrument. The replacement chips, as well as the service process, were designed and developed under a formal quality system ensuring the serviced instruments meet the quality and functional requirements of a new device. Formal, independent testing and validation on the replacement chips were conducted to ensure the intended use and performance are equivalent to that of the new OEM device.

What do we need to know to collect instruments for service?

Upon receiving an instrument for the initial repair, the instrument must have at least one use left on the counter. If the original instrument reaches zero (0) it cannot be serviced. In order for the reset to be performed, the data must be retained on the initial repair. However, once the reset has been performed once, the instrument can be used up to expiration (zero) and still retain its original data and the ability to be reset.

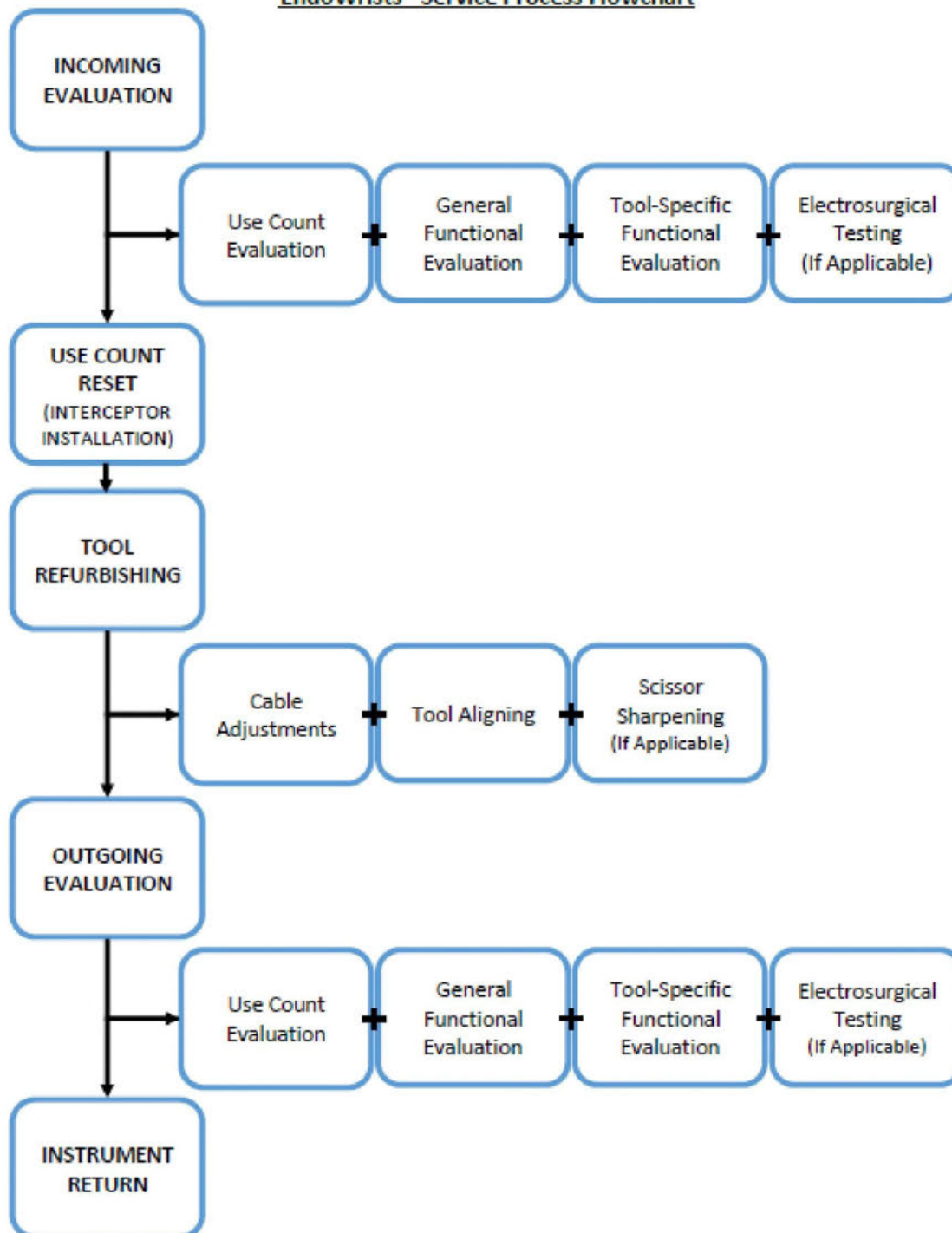
What instrument models are supported?

Compatible EndoWrist® Instruments

420001 Potts Scissors
420003 Small Clip Applier
420006 Large Needle Driver
420007 Round Tip Scissors
420033 Black Diamond Micro Forceps
420036 DeBakey Forceps
420048 Tip Forceps
420049 Cadere Forceps
420093 ProGrasp Forceps
420110 PreCise Bipolar Forceps
420121 Fine Tissue Forceps
420157 Snap-fit™ Scalpel Instrument
420171 Micro Bipolar Forceps
420172 Maryland Bipolar Forceps
420178 Curved Scissors
420179 Hot Shears (Monopolar Curved Scissors)
420181 Resano Forceps
420183 Permanent Cautery Hook
420184 Permanent Cautery Spatula
420189 Double Fenestrated Grasper
420190 Cobra Grasper
420192 Valve Hook
420194 Mega Needle Driver (Tapered)
420203 Pericardial Dissector
420204 Atrial Retractor
420205 Fenestrated Bipolar Forceps
420207 Tenaculum Forceps
420215 Cardiac Probe Grasper
420227 PK® Dissecting Forceps
420230 Large Clip Applier
420246 Atrial Retractor Short Right
420249 Dual Blade Retractor
420278 Graptor (Grasping Retractor)
420296 Large SutureCut™ Needle Driver
420309 Mega™ SutureCut™ Needle Driver
420318 Small Graptor (Grasping Retractor)
420327 Medium-Large Clip Applier
420344 Curved Bipolar Dissector

Can you describe your service process?

EndoWrists® Service Process Flowchart



Additional information:

- EndoWrist® functionality and safety are not affected by the repair
 - Extensive analysis and formal testing were performed to ensure the proper function and performance
 - Repaired instruments have been subjected to, and passed, all appropriate ISO 10993 biocompatibility tests (by a certified independent test laboratory)
 - Electrical and electrosurgical safety have been carefully considered per the expectations in the safety standards, and special fixtures are used during service to retest the instrument to a production equivalent qualification
- Service components are built to medical device quality standards, including:
 - ISO 9001: Quality Systems Model for QA in Design/Development, Production, Installation, and Servicing
 - ISO 9002: Quality Systems Model for QA in Production and Installation
 - ISO 9003: Quality Systems Model for QA in Final Inspection and test
 - ISO 9001: Quality Management Systems
- The service process is performed under a formal quality control system certified per ISO 9001, with all assembly operations and testing performed per formal procedures
- SIS provides continuing technical support to assure the final quality of the serviced instruments, and will monitor and respond to any reported field issues using a formal surveillance system
- Validated fixtures and tools can be provided to repeat safety testing in the hospital, if desired



da Vinci® EndoWrist® Repairs

Stop throwing away money on your da Vinci® EndoWrist® devices!

SIS can now service your da Vinci® devices including repair and use counter reset.

Important facts:

- The da Vinci® EndoWrist® is a “multi-use” medical device. Multi-use devices, such as endoscopic instruments, have always been eligible for repair.
- The repair of da Vinci® EndoWrist® does not alter the intended use, method of use, functionality or performance of the device in any way.
- The da Vinci® Robot interacts with the repaired EndoWrist® identically and the robot cannot be affected by the repaired device in any way.
- The robot communicates with the EndoWrist® prior to surgery only. Prior to surgery, the robot confirms the serial number, model number and remaining uses. The repaired device will function identically to the new OEM EndoWrist®.
- A repaired EndoWrist® is not an alternative or replacement device. It is an original da Vinci® manufactured device that has been repaired to original specifications.

It's time to challenge the status quo

SIS da Vinci® EndoWrist® repair services will boost your bottom line and help provide the prompt and tailored responses your OR demands.

Call your local SIS representative or our Corporate Office at 800.747.8044.



da Vinci® EndoWrist® Repair Process

When sending in your DaVinci EndoWrist® devices to SIS for repair, it is important to follow all the instructions below.

All devices must go through the decontamination process before they are collected for service by SIS. The devices do not need to be sterile.

Initial Service on an EndoWrist® (Si & S) Device

- The EndoWrist® must be sent in with one click remaining. This is only required for the initial service of the EndoWrist®. Once the device has been serviced by SIS, the counter can be run to zero.
- If an EndoWrist® is being sent for its initial service with SIS, place a red sticker on the body of the device.
- Place EndoWrist® into the SIS collection container
- Devices will be collected by your local SIS representative and shipped to the SIS National Service Center.
- Devices will be tested, refurbished to OEM performance specifications, and reset for 10 additional uses. During the refurbishment process, a code will be etched on the device.
- Once repaired, the device will be returned to your facility by your local SIS representative.

Ongoing Service of EndoWrist® (Si & S) Devices (applies only to devices that have been previously serviced by SIS)

- Device to be collected with zero clicks remaining (device is "expired")
- Place EndoWrist® into the SIS collection container
- Devices will be collected by your local SIS representative and shipped to the SIS National Service Center.
- Devices will be tested, refurbished to OEM performance specifications, and reset for 10 additional uses.
- Once repaired, the device will be returned to your facility by your local SIS representative.

EndoWrist® (Xi, Si & S) Device Collection for Parts and Testing

- All Xi devices
- Si and S devices that have zero clicks or have expired and not been serviced prior by SIS (not etched)
- Place devices in the SIS collection container
- Devices will be collected by your local SIS representative and shipped to the SIS National Service Center.



Surgical Instrument Service Co., Inc.

Summary of Quality and Reliability Measures

BACKGROUND

SIS da Vinci® repair is a specialized process for the EndoDevice® instruments of the da Vinci® surgical robot to extend their safe and effective life beyond the uses recommended by the original equipment manufacturer. SIS services the devices by installing a resettable use counter while maintaining the ability of the da Vinci™ Surgical Robot to access all data in the OEM memory and to count uses as usual.

These devices are not single use devices. The materials in the instruments are durable and commonly used in other reusable medical devices. Testing of the instruments after many additional usage cycles indicated no trend of material deterioration beyond normal tool wear.

The intended use, method of use, functionality, or performance of the instrument are not changed by this service. The original data required by the machine to communicate with the instrument is not altered in any way. The machine will still recognize the model number, serial number, and instrument being used. Additionally, the data read from the instrument is clearly displayed and verified by the user and robot prior to surgery. Data is not read during surgery.

QUALITY SYSTEM INFORMATION

The quality management system has been approved by the notified body DQS Medizinprodukte GmbH according to ISO 13485:2003 and MDD 93/42/EEC MOD 5 compliant system.

The quality management system has been approved and is currently certified by the notified body Global Group according to ISO 9001:2015.

SERVICE PROCESS DEVELOPMENT

The da Vinci® S/Si instruments are sold with an arbitrary use counter, which limits usage to a certain number of procedures. Upon reaching zero, the instruments are considered “expired” and must be discarded. Our service provides the ability to extend the useful life of the instrument. The service process involves a complete evaluation, repair, and test of the instrument.

The SIS EndoWrist® service was designed for the da Vinci® S/Si Device Instruments, the OEM chip, and robot interface to perform in the same manner as the OEM original. This service does not affect the instruments form, fit or function.

The applicable products are outlined on the following pages (this list may be updated as new products are approved for repair):

REF	USES	DESCRIPTION
420001	10	Potts Scissors
420003	100	Small Clip Applier
420006	10	Large Needle Driver
420007	10	Round Tip Scissors
420033	15	Black Diamond Micro Forceps
420036	10	DeBakey Forceps
420048	10	Long Tip Forceps
420049	10	Cadiere Forceps
420093	10	ProGrasp Forceps
420110	10	PreCise Bipolar Forceps
420121	15	Fine Tissue Forceps
420157	30	Snap-fit™ Scalpel Instrument

420171	10	Micro Bipolar Forceps
420172	10	Maryland Bipolar Forceps
420178	10	Curved Scissors
420179	10	Hot Shears (Monopolar Curved Scissors)
420181	10	Resano Forceps
420183	10	Permanent Cautery Hook
420184	10	Permanent Cautery Spatula
420189	10	Double Fenestrated Grasper
420190	10	Cobra Grasper
420192	15	Valve Hook
420194	10	Mega Needle Driver (Tapered)
420203	10	Pericardial Dissector
420204	10	Atrial Retractor

420205	10	Fenestrated Bipolar Forceps
420207	10	Tenaculum Forceps
420215	10	Cardiac Probe Grasper
420227	10	PK® Dissecting Forceps
420230	100	Large Clip Applier
420246	10	Atrial Retractor Short Right
420249	10	Dual Blade Retractor
420278	10	Graptor (Grasping Retractor)
420296	10	Large SutureCut™ Needle Driver
420309	10	Mega™ SutureCut™ Needle Driver
420318	10	Small Graptor (Grasping Retractor)
420327	100	Medium-Large Clip Applier
420344	10	Curved Bipolar Dissector

Risk Management

Risk management activities per ISO 14971 standard were performed during the development, verification and validation of service processes. Post-production monitoring of the devices serviced by SIS will ensure this service remains free from safety concerns. The risk management process identifies, estimates, and evaluates the serviced product's safety risks, methods to control these risks, and to verify the effectiveness of these controls. A detailed FMEA (Failure Modes and Effects Analysis) was performed covering the service process.

Development Process

Extensive validation and safety testing occurred during the development of the service process (see below). Both the development of the service process and the ongoing repair operations are performed under the appropriate certified quality systems. A complete technical file describing qualification activities and independent testing was created and informed the development of formal procedures to guide the service operations performed.

The following list of standards was considered and applied to the development process:

Standard #	Year	Title
EN 980	2008	Symbols for use in the labeling of medical devices
EN 1041	2008	Information supplied by the manufacturer of medical devices
EN ISO 10993-1	2009	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 10993-4	2009	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood
EN ISO 10993-5	2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10	2010	Biological evaluation of medical devices – Part 10: Tests for Irritation and Skin Sensitization
EN ISO 10993-11	2009	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity

EN ISO 10993-12	2012	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
EN ISO 13485	2012 & AC: 2012	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971	2012	Application of risk management to medical devices
EN ISO 14937	2009	Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
EN ISO 17664	2004	Sterilization of medical devices – Information to be provided by the manufacturer for the processing of re-sterilizable medical devices
EN ISO 17665-1	2006	Sterilization of health care products – Moist Heat – Part 1: Requirements for the development, validation and routine control of a sterilizer for medical devices (reference only)
EN ISO 17665-2	2009	Sterilization of health care products – Moist Heat – Part 2: Guidance on the application of ISO 17665-1 (reference only)
EN 60601-1	2006	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN 60601-1-2	2007	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
EN 60601-2-2	2009	Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
EN 62304	2006	Medical device software – Software life-cycle processes
EN 62366	2008	Medical devices – Application of usability engineering to medical devices

BIOLOGICAL EVALUATION

The material and microbiological characteristics of devices that have been serviced have been evaluated to determine whether they demonstrate any biocompatibility risk. It has been assumed that the OEM devices were marketed as biocompatible.

Tests were conducted with devices serviced to demonstrate compliance to the following standards:

Test	Standard	Report #
ISO MEM Elution Assay with L-929 Mouse Fibroblast Cells	<ul style="list-style-type: none"> ISO 10993-5: 2009 Biological Evaluation of Medical Devices, Part 5: Tests for In Vitro Cytotoxicity ISO 10993-12: 2012 Biological Evaluation of Medical Devices, Part 12: Sample Preparation and Reference Materials 	5107 and 5109
ASTM Hemolysis – Extract Method (GLP)	<ul style="list-style-type: none"> ASTM Guideline F619-03, reapproved 2008. Standard Practice for Extraction of Medical Plastics. 2012. Annual Book of ASTM Standards, Volume 13.01:223-226 ISO 10993-4: 2002 and Amendment 1, 2006. Biological Evaluation of Medical Devices, Part 4: Selection of Tests for Interaction with Blood ISO 10993-12: 2012 Biological Evaluation of Medical Devices, Part 12: Sample Preparation and Reference Materials 	4349 and 4350
ISO Guinea Pig Maximization Sensitization Test (GLP-2 Extracts)	<ul style="list-style-type: none"> ISO 10993-10: 2010 Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization, pp. 18-26 ISO 10993-12: 2012 Biological Evaluation of Medical Devices, Part 12: Sample Preparation and Reference Materials 	5003 and 4981
ISO Acute Systemic Injection Test (GLP-2 Extracts)	<ul style="list-style-type: none"> ISO 10993-11: 2006 Biological Evaluation of Medical Devices, Part 11: Tests for Systemic Toxicity ISO 10993-12: 2012 Biological Evaluation of Medical Devices, Part 12: Sample Preparation and Reference Materials 	4498 and 4501

ISO Intracutaneous Irritation Test (GLP-2 Extracts)	<ul style="list-style-type: none"> ISO 10993-10: 2010 Standard, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization, pp. 11-14 	4316 and 4317
	<ul style="list-style-type: none"> ISO 10993-12: 2012 Biological Evaluation of Medical Devices, Part 12: Sample Preparation and Reference Materials 	

The test results revealed no unacceptable levels of toxicity or irritation. All test samples demonstrated the necessary biocompatibility characteristics.

Cleaning and sterilization

The serviced devices are not provided in a sterile condition. However, they do require cleaning and sterilization prior to clinical use per the OEM IFU. There are no changes to these processes, which are performed between surgeries at the hospital. In order to ensure that sterilization instructions remain valid for the devices serviced, they have completed both cleaning and sterilization qualification studies. These studies were performed by a third party specializing in the cleaning and sterilization processes. The final results demonstrate that the recommended procedures ensure adequate cleaning and sterilization for end users of the devices.

ELECTRICAL AND ELECTROSURGICAL SAFETY

Electrical/Electrosurgical safety testing has been conducted using a third party independent test lab to verify serviced devices meet applicable environmental, safety and labeling requirements.

Tests were performed using devices serviced to demonstrate compliance to the standards listed on the following page:

Standard Document	Description
IEC 60601-1: 2005 & A1: 2012	Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-2-2: 2009	Medical Electrical Equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
EN 60601-1-2: 2007	Medical Electrical Equipment: General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests.

The results demonstrate compliance with the applicable requirements of the aforementioned safety standards for medical devices.

USABILITY ENGINEERING

The services have been designed to maintain the exterior specification, connection, use application, user profile, or frequently used functions, when compared to the original devices produced by the OEM. We have considered the impact of the safety and labeling requirements for the end users. One additional challenge to the labeling integrity was conducted during the electrical safety testing by SGS. Those results demonstrated legibility following an intentional rub down test.

RELIABILITY/PERFORMANCE TEST SUMMARY

A worst-case analysis was carried out to determine which models should be used during performance and life testing. Although each tool is unique, there are four basic mechanical function/tool end designs: Scissors, Graspers, Needle Drivers and Non-Opening (tool ends that do not open and close).

In addition, certain models deliver RF energy (“Energized Device”). Energized Devices are either Monopolar, Bipolar or PlasmaKinetic™ (PK™). For each Tool End Design, an Energized Device is considered worst case because RF energy represents a greater stress/challenge to the tool end. Representative models

were chosen based on Tool End Design, Energized Device models and general market popularity.

Initially, a quantity of each representative model was characterized by their mechanical and functional properties. New OEM instruments were analyzed to provide baseline statistics and information. Examples of such statistics include, but were not limited to:

- Tool end range of motion
- Tool end functional performance (e.g. grasping performance and cutting performance)
- RF energy effectiveness
- Electrical safety testing
- General instrument condition
- Effective communication and use counting on the host system

Following the OEM characterization, instruments with one remaining use underwent the repair process. Immediately following the repair process, the instruments were subjected to the same baseline testing in order to establish equivalence. Formal life-testing was then conducted to simulate an additional 10 uses. The life testing subjected the instrument to 10 simulated surgical environments to test each aspect of the individual instrument's functional capabilities. After each of the simulated uses, the instruments were subjected to the normal cleaning and sterilization procedures provided by the OEM. At different intervals, and at end-of-life, the instrument was subjected to the same battery of testing. The testing showed no degradation in performance or condition of the instruments. The formal protocols executed reside in the technical file per the ISO 13485 quality system used for development; these files were independently reviewed by DQS, a certified EU notified body assessor for medical devices.

Additionally, this repair process was repeated and a battery of tests was performed on the same batch of instruments. This brought the total number of uses experienced by the instruments to 29. This includes the 9 original uses on the OEM device, 10 additional uses following first repair service, and another 10 uses following the second repair process. The reliability testing following two repair services showed no trend of degradation in the performance or condition

of the instruments, therefore no further cycles under this formal protocol were conducted.

The test results revealed that all acceptance criteria have been achieved and the sample devices demonstrate sufficient performance and safety characteristics in order to confidently release the devices to distribution. Also, a worst-case verification test has been performed on the flush tube, a component of all devices, to ensure it has been adequately challenged in an effort to confirm the environmental conditions of use do not adversely affect the component and related performance expectations.

During further analysis for reliability, disassembled OEM instruments and their components underwent material analysis by experts in medical device design and construction. The instruments' materials were surgical grade metals or well-established thermoplastics already being utilized in other multiple-use surgical instruments.

Following the formal testing described above, a smaller batch of representative models were subjected to over 50 cleaning and sterilization cycles to demonstrate the robust nature of the instrument's design. Similar inspection and testing was carried out on these devices, and, as expected, no indications of material degradation were observed.

FUNCTIONAL VERIFICATION AND VALIDATION

Approach

Several compatibility and functional validations were conducted of the replacement chip for use with the da Vinci® S and da Vinci® Si Surgical Systems. Such validations included utilizing OEM instruments to characterize the timing and types of communications between the instrument and the host system. These same instruments were then repaired, and the replacement chip installed. The repaired instruments were then subjected to the same characterization on the same host systems to validate their equivalence. These validations showed equivalence in all instrument models and on both the S and Si Surgical Systems.

Functional testing included extensive formal protocols following regulatory expectations for medical device software testing (there is no software inside the instrument, but it interfaces to the software inside the robot itself via a simple data bus). Reputable third-party experts were utilized to ensure rigorous and independent validation.

EXHIBIT 2
to
DECLARATION OF ANDREW LAZEROW IN SUPPORT OF
INTUITIVE SURGICAL INC.'S OPPOSITION TO SIS'S
MOTION IN LIMINE #5

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA**

SURGICAL INSTRUMENT SERVICE
COMPANY, INC.,

Plaintiff/Counter-Defendant,

v.

INTUITIVE SURGICAL, INC.,

Defendant/Counter-Claimant.

Case No. 3:21-cv-03496-VC

Honorable Vince Chhabria

Complaint filed: May 10, 2021

OPENING EXPERT REPORT OF PHILIP J. PHILLIPS
HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY
DECEMBER 2, 2022

or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term “device” does not include software functions excluded pursuant to section 520(o). A device, as that term is defined, is basically a healthcare product that fulfills its medical purpose by physical and/or mechanical means, rather than through chemical and/or metabolic activity.

18. Although the definition of the term “device” includes “any component, part, or accessory,” in reality FDA does not actively regulate all device components, parts, and accessories but rather focuses its attention on those that are “ready to be used for any intended health-related purpose and are packaged or labeled for commercial distribution for such health-related purpose ...” [21 CFR § 820.20(a)(6)]. Illustrations of components regulated by FDA that are cited include blood filters and dialysis tubing that are required for device functionality and are packaged, labeled and are commercially distributed directly to users. From a quality systems standpoint, the term “component” is defined more broadly to include the term “part” [21 CFR § 820.3(c)], however the relevance of the definition pertains to device manufacturers’ responsibilities to ensure that any components and parts incorporated into a finished device are suitable for their intended purpose and fulfill relevant requirements. Very few device components and parts are subject to registration and listing requirements and premarket notification.

19. Medical devices are regulated by FDA through a classification system based on the risk(s) posed by the product, the existing knowledge related to the product’s intended use and technology, and the level of regulatory control needed to adequately assure safety and effectiveness.⁶

20. The objective of FDA device regulation is to provide the American public with reasonable assurance of the safety and effectiveness for all medical devices introduced into interstate commerce.⁷ The basic framework for achieving this objective rests on a classification system in which a particular device’s class designation dictates the applicable regulatory

⁶ 21 U.S.C. § 360c.

⁷ 21 U.S.C. § 393(b).

requirements. FDA’s approach to assuring safety and effectiveness depends upon the class of the device, and varies with the level of concern that FDA has regarding the adequacy of the available regulatory controls to provide this assurance.

21. The Federal Food, Drug, and Cosmetics Act (“FDCA” or “the Act”)⁸ defines three classes of medical devices: class I, class II, and class III. Class I devices are simple products that usually present minimal potential for harm to the patient.⁹ These devices are subject to “general controls,” a set of controls applicable to virtually all devices, and which involve the least amount of regulation by FDA. General controls include labeling, provisions against adulteration and misbranding, good manufacturing practices (“GMPs”), establishment registration, medical device listing, and premarket notification prior to marketing a device, among others.¹⁰ FDA has since exempted most class I devices from section 510(k) requirements of the Act pursuant to the authority provided by 21 U.S.C. § 360c(d)(2)(A).

22. In general, class II devices present a greater level of potential risk than class I devices. In addition to general controls, class II devices may be subject to additional special controls to provide a “reasonable assurance” of safety and effectiveness.¹¹ Special controls may include special labeling requirements, mandatory performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (such as for providing clinical data in 510(k) submissions), recommendations, and any other actions that the Secretary of Health and Human Services determines are necessary to provide a reasonable assurance of safety and effectiveness.

23. Under the Act, class III devices are those devices purported or represented to support or sustain human life, to be of substantial importance in preventing impairment of human health, or to present a potential unreasonable risk of illness or injury to patients.¹² Class III devices are therefore subject to the highest levels of FDA’s regulatory controls, including general controls

⁸ 21 U.S.C. § 301 *et seq.*

⁹ 21 U.S.C. § 360c(a)(1)(A).

¹⁰ 21 U.S.C. §§ 351, 352, 360, 360f, 360h, 360i, and 360j.

¹¹ 21 U.S.C. § 360c(a)(1)(B).

¹² 21 U.S.C. § 360c (a)(1)(C)(ii).

and any relevant special controls, and must undergo a rigorous FDA review process called premarket approval.¹³ Independent of the statutory criteria for regulating a device in class III, all new devices are class III by operation of law unless FDA has classified them into class I or class II, or has determined the new device to be substantially equivalent (“SE”) to a device previously classified in class I or class II by regulation or through the 510(k) process.¹⁴

24. FDA regulation of devices provides a “reasonable assurance of safety and effectiveness.” What constitutes a reasonable assurance of safety is described in 21 C.F.R. § 860.7(d)(1) as follows:

“There is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions of use.”

25. What constitutes a reasonable assurance of effectiveness is described in 21 C.F.R. § 860.7(e)(1) as follows:

“There is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.”

26. In assuring safety and effectiveness of devices, FDA is required to consider four factors: (1) the persons for whom the device is represented or intended, (2) the conditions of use for the device, (3) the probable benefits versus probable risks, and (4) the reliability of the device.¹⁵

¹³ 21 U.S.C. § 360e.

¹⁴ 21 U.S.C. § 360c(f).

¹⁵ 21 C.F.R. § 860.7(b)(1)-(4).

are shipped to an ultimate consumer, i.e., a lay person (for “over-the-counter” devices) or a licensed healthcare provider/healthcare facility (for “prescription” devices). The usage counter reset circuit board that SIS intended to insert into a serviced EndoWrist instrument has no “health-related purpose” as illustrated in the regulation and I am not aware of any chip labeling that suggests that one could exist.

C. The submission of a 510(k) and an FDA clearance by others does not establish that either is in fact necessary or required for SIS’s repair services.

117. Unnecessary 510(k)s are regularly submitted to FDA for a myriad of reasons.⁴⁴ It is well known that individuals and companies submit 510(k)s that are unnecessary and that FDA regularly finds the subjects of what may be unnecessary 510(k)s to be SE.

118. In accordance with 21 CFR § 807.100(b), the focus of a 510(k) review is always a device and how it compares to a legally marketed predicate device. The circumstances under which the device is created is not a consideration in whether it is SE to a predicate device. In fact, there is no requirement that manufacturing information be included in a 510(k) submission.⁴⁵

119. I understand that Rebotix filed a 510(k) and withdrew it after receiving a request for additional information from FDA. Although the additional information request stated that the device that is the subject of the submission cannot be marketed until FDA finds it SE, as I established in paragraph 37 of this report, the statement is boilerplate language that the Agency always uses in additional information requests and it means nothing in the context of a device that does not require 510(k) clearance in order to be marketed.

120. On September 30, 2022, FDA cleared 510(k) number K210478 for Iconocare Health’s “8mm Monopolar Curved Scissors.” Based on the 510(k) Summary that is available on FDA’s publicly available database⁴⁶, it is clear that Iconocare Health is engaged in a “reprocessing” activity involving Intuitive Surgical’s Da Vinci S/Si EndoWrist Instruments and

⁴⁴ Phillips, PJ and Lynne, JC. 2005. Unnecessary 510(k) Filings: A Waste of FDA and Industry Resources. *Regulatory Affairs Journal (Devices)* 13:341-345.

⁴⁵ 21 CFR § 807.87

⁴⁶ Available at https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210478.pdf

Accessories⁴⁷, although details of the activity that were revealed to FDA in the 510(k) submission are unknown. The following FDA conclusion is very insightful and requires analysis:

“The design, materials, and intended use of the 8mm Monopolar Curved Scissor Instruments, after an additional ten (10) reuse cycles are equivalent to the predicate device. The mechanism of action of the subject device is identical to the predicate device in that the same standard mechanical design, materials, and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, or method of operation. The change in device specifications is to extend the useful life of the 8mm Monopolar Curved Scissor Instruments.”

121. First, it is obvious that Iconocare Health has extended the useful life of an Intuitive Surgical device beyond the 10-use limit imposed by Intuitive Surgical. Iconocare Health demonstrated to FDA’s satisfaction that modifying and relabeling each “presumably used” Intuitive Surgical device to create a “new” device, with an additional 10 uses, is SE to the predicate devices. This clearly establishes that the “intended use” of the Intuitive Surgical’s legally marketed EndoWrist device is the same as the intended use of Iconocare Health’s newly cleared device. Second, it is clear that FDA considered the extension of the useful life of the 8mm Monopolar Curved Scissor Instruments by 10 uses as a change in “device specifications” and not a change in intended use. In this regard, even though the specifications are identical, it appears that Iconocare Health provided performance data to FDA that demonstrated that “... the reprocessed devices are as safe and effective as the predicate and operate as originally intended.” Furthermore, the company convinced FDA that testing each individual device before release establishes the “... appropriate function of its components prior to packaging and labeling operations.” It is not surprising that FDA determined the device to be SE as it is virtually identical to the predicate devices in all respects and one would anticipate that they are as safe and effective. The result of this SE determination is that FDA expects that Iconocare Health will fulfill all medical device

⁴⁷ Five Intuitive Surgical 510(k) clearances are identified as predicate devices, specifically, K180033, K050369, K081177, K123329, and K170644

requirements, including registration and listing as required by 21 § CFR 807, filing 510(k)s for future changes and modifications to the device as required by 21 CFR § 807.81(a)(3), properly labeling their devices for commercial distribution as required by 21 CFR § 801 and meeting quality system requirements in accordance with 21 CFR § 820. In its 510(k) summary, FDA did not refer to Iconocare Health as a “remanufacture”, but rather as a “reprocessor.” On the basis of the information that is publicly available, it is not obvious that FDA made a legal or regulatory decision that Iconocare Health’s activities constituted “remanufacturing” and that a 510(k) was required. Furthermore, there is no reason to believe that this 510(k) clearance has any relevance to SIS’ situation except in one respect; SIS cannot remanufacture, relabel and repackage Intuitive Surgical EndoWrist instruments and commercially distribute them on the open market under its own name. Iconocare Health can do so. The regulatory status of any other activities undertaken by Iconocare Health are uncertain.

122. In December 2021, Intuitive Surgical submitted a 510(k) for changes to the da Vinci X/Xi 8mm Reusable Instruments to increase the number of lives (uses) and reprocessing cycles. [Intuitive 02053646] Intuitive Surgical had concluded that the change did not require FDA premarket authorization and the change had already been implemented with modified devices being placed in commercial distribution. According to Intuitive Surgical employee Thomas E. Claiborne, Ph.D., the 510(k) was submitted at the verbal request of an FDA employee with the understanding that the Agency would exercise “enforcement discretion,” i.e., not take an enforcement action against the company for marketing an illegal device, while the 510(k) was under review. As discussed in paragraph 38, the submission of this 510(k) is not evidence that the change was of a nature that “could significantly affect safety and effectiveness” and required a 510(k) clearance. Based on the deposition of Dr. Claiborne, there was a disagreement between Intuitive Surgical and an FDA employee regarding the significance of the change and the 510(k) was submitted to avoid any conflict.

EXHIBIT 3
to
DECLARATION OF ANDREW LAZEROW IN SUPPORT OF
INTUITIVE SURGICAL INC.'S OPPOSITION TO SIS'S
MOTION IN LIMINE #5

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA**

HIGHLY CONFIDENTIAL: SUBJECT TO PROTECTIVE ORDER

SURGICAL INSTRUMENT SERVICE
COMPANY, INC.,

Plaintiff,

vs.

INTUITIVE SURGICAL, INC.,

Defendant.

)
)
)
)
)
)
)
)
)
)

Case No. 5:21-cv-03496.

EXPERT REPORT

**Dr. Russell L. Lamb
President**

Monument Economics Group, LLC
1000 Wilson Boulevard
Suite 2650
Arlington, VA 22209

December 2, 2022

Accessories.”³⁰³ The Intuitive Service Agreement also stated that the license to use an EndoWrist instrument with the da Vinci surgical robot purchased by the hospital “expires once an Instrument or Accessory is used up to its maximum number of uses, as is specified in the Documentation accompanying the Instrument or Accessory.”³⁰⁴ At deposition, Mr. Vavoso testified that he understood this term of the Intuitive Service Agreement to mean that the EndoWrist “instruments have a designated number of lives. And once those lives are used, then the license has expired.”³⁰⁵ I understand that Intuitive claims that this requirement was necessary due to patient safety concerns associated with allowing third parties to repair its EndoWrist surgical instruments.³⁰⁶

129. I understand that, in his expert report in this matter, Plaintiff’s regulatory expert, Mr. Philip J. Phillips, addresses a recent action taken by the FDA with respect to 510(k) clearance for the marketing of reprocessed Intuitive Surgical da Vinci model S/Si EndoWrist instruments by a company called Iconocare Health (“Iconocare”).³⁰⁷ In its September 2022 letter to Iconocare, the FDA concluded:

The design, materials, and intended use of the 8mm Monopolar Curved Scissor Instruments, after an additional ten (10) reuse cycles are equivalent to the predicate device. The mechanism of action of the subject device is identical to the predicate device in that the same standard mechanical design, materials, and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, or method of operation. The change in device specifications is to extend the useful life of the 8mm Monopolar Curved Scissor Instruments.³⁰⁸

³⁰³ Vavoso Deposition at 194:11-195:11, Exhibit 24 at Intuitive-00067540. Glenn Vavoso of Intuitive testified that he was not “aware of any contract with any hospital that does not include this use of system term.” See Vavoso Deposition at 195:4-11.

³⁰⁴ Vavoso Deposition at 195:17-196:14, Exhibit 24 at Intuitive-00067542. At deposition, Glenn Vavoso of Intuitive was unable to “identify any sales contract with the hospital that does not include the language in paragraph 8.” See Vavoso Deposition at 198:24-199:2.

³⁰⁵ Vavoso Deposition at 196:15-197:6.

³⁰⁶ See, for example, Deposition of Myriam Curet MD, May 7, 2021 (hereafter “Curet Deposition”) at 107:7-25.

³⁰⁷ Telephone conversation with Mr. Philip J. Phillips, dated December 1, 2022.

³⁰⁸ FDA, Letter to Iconocore Health, “RE: K210478,” dated November 15, 2022. Available at https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210478.pdf.

I understand that Mr. Phillips opines that Iconocare demonstrated to FDA's satisfaction that modifying and relabeling each presumably-used Intuitive device to create a reprocessed device, with an additional 10 uses, is substantially equivalent to the predicate devices.³⁰⁹ I understand that, in Mr. Phillip's opinion, this establishes that the "intended use" of Intuitive's marketed EndoWrist device is the same as the intended use of Iconocare Health's newly-cleared device.³¹⁰

130. I understand Mr. Phillips concludes that Iconocare provided performance data to the FDA that demonstrated that the reprocessed devices are as safe and effective as the predicate devices and operate as originally intended.³¹¹ I also understand that Mr. Phillips further asserts that it is not surprising that FDA determined the Iconocare EndoWrist device to be substantially equivalent, as it is virtually identical to the predicate devices in all respects and one would anticipate that they are as safe and effective.³¹² Based on Mr. Phillip's analysis of the FDA's recent clearance of reprocessed EndoWrist instruments, I understand Mr. Phillips has concluded that Intuitive's claims that it is unsafe to use EndoWrist surgical instruments more than the maximum number of times imposed by Intuitive appears to be inconsistent with the determination made recently by the FDA.

131. For the purposes of my analysis contained in this Expert Report, I rely on the opinions of Mr. Philip Phillips regarding the FDA's assessment of the safety of reprocessed EndoWrist surgical instruments as compared to Intuitive's newly manufactured replacement EndoWrist surgical instruments. Additional evidence I have reviewed is consistent with Mr. Phillips' conclusions regarding the FDA's assessment of the safety of reprocessed EndoWrist instruments. For example, at deposition, Nicky Goodson, Senior Director for Service Operations at Intuitive, testified that Intuitive has not done testing of any kind to determine whether refurbished or repaired EndoWrists

³⁰⁹ Telephone conversation with Mr. Philip J. Phillips, dated December 1, 2022.

³¹⁰ Telephone conversation with Mr. Philip J. Phillips, dated December 1, 2022.

³¹¹ Telephone conversation with Mr. Philip J. Phillips, dated December 1, 2022.

³¹² Telephone conversation with Mr. Philip J. Phillips, dated December 1, 2022.

EXHIBIT 4
to
DECLARATION OF ANDREW LAZEROW IN SUPPORT OF
INTUITIVE SURGICAL INC.'S OPPOSITION TO SIS'S
MOTION IN LIMINE #5



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

K143619/S002
Rebotix, LLC
Remanufactured EndoWrists

June 23, 2015

Device Description

1. You state that the subject device is reusable (for 11 additional uses), is provided non-sterile to the user, and must be cleaned and sterilized before the first and each subsequent use. However, there is no description of any of the cables used with the electrosurgical devices. We note that page 24 of the Instructions for Use states, "The PK Instrument Cords are reusable for a maximum of twenty (20) reuse cycles. Therefore, it is not clear if any of the cords for the electrosurgical instruments are included in the submission and, if so, how they are remanufactured or reprocessed by Rebotix, how they will be supplied to the end user, and how they will be reprocessed by the end user. If the cords are included in the submission, please provide all details regarding the device description, remanufacturing process, validated reprocessing instructions for users, and validated number of use lives, or a method to assess the cord's end of life based on simulated use/reprocessing followed by performance testing.

Remanufacturing

The following deficiencies refer to the procedures you have identified to collect used devices from users, and modify those devices to accommodate additional uses (defined as "remanufacturing" for the purpose of this letter).

2. Although the subject device is not a "single-use device" (defined as a device used only once and then discarded), it has many aspects in common with third party reprocessed single-use devices. Therefore, it is recommended that you review and provide the following items described in FDA's Guidance "Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices," (available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071434>):
 - a. Cleaning Agent Characterization
 - b. Process and Equipment Characterization
 - i. Cleaning process tolerances have not been described, nor have quality control tests or equipment specifications. It is recommended that the tolerances for each cleaning process be provided in a tabular format that

lists the minimum, maximum, and nominal values for each relevant parameter.

- c. Risk Analysis
 - d. Process Validation that includes Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification
 - i. It does not appear that the cleaning processes described in the remanufacturing procedures have been validated.
 - ii. In addition, the IQ and OQ for the sterilization process have not been provided.
 - e. Routine Monitoring and Control
 - f. Assessment of Change
 - i. Procedures to track changes that occur with the original equipment manufacturer (OEM) device as well as OEM reprocessing changes should be implemented. Please refer to Deficiencies 3b, 35a, 39, and 42b for more information.
3. In Attachment D of Supplement 2, you provide the protocols for your remanufacturing procedures. Please revise the protocols as described below and provide a copy with your response.
- a. Protocol PR3034, Autoclave Sterilization, appears to include non-discrete temperatures and times (e.g., temperature ranges, minimum exposure times) for steam sterilization. Please revise the procedures under PR3034 to include discrete temperatures and times that match your sterilization validation activities. Please also see Deficiency 14h below for similar issues regarding non-discrete values in the reprocessing instructions.
 - b. Protocol PR3043, Incoming Evaluation, states that candidates for remanufacture are evaluated for acceptance. Please address the following concerns regarding this protocol:
 - i. There is no explanation of how clinical soil on the received devices will be assessed and any related acceptance criteria. It is not clear if devices shipped from the health care facilities will be reprocessed before shipping or if they are shipped dirty. Please clarify these issues and revise your Incoming Evaluation protocol to include inspection criteria related to soil. The incoming acceptance criteria should be based on the results from your cleaning and sterilization validation studies, which should demonstrate that clinically used devices with worst case soiling (as

determined from a Native Soil Characterization Study) can be effectively cleaned and sterilized. Please see related Deficiencies 18 and 19 regarding the Native Soil Characterization Study for more information.

- ii. It does not appear that you have methods in place to track OEM device and reprocessing changes. Please revise your Incoming Evaluation protocol to include acceptance criteria for OEM device changes and reprocessing changes that are acceptable or not acceptable. FDA expects that you collect and track information from the health care facilities and only accept devices that fit within the scheme of devices that were validated for remanufacturing; this information should also be stated in the labeling (please see related Deficiency 5 below). For example, if OEM devices that were reprocessed by cleaning, disinfection AND sterilization were not included in your verification and validation testing, then these devices should not be accepted for remanufacturing since it could affect the use life, safety, and effectiveness of the device. It is also expected that this tracking be an ongoing monitoring procedure that is in place.
 - iii. Please revise your Incoming Evaluation protocol to include a criterion for previously remanufactured devices, including an explanation for how these devices are identified and that they will not be forwarded to the next remanufacturing step.
- c. Protocol PR3033, Disassembly and Salvage, states that the small bearing and large bearing should be re-lubricated if necessary. However, it is not clear what these components are and if they are patient-contacting (including indirect patient contact due to cleaning fluid contact and travel down the instrument). In addition, it is not clear what lubricant is applied and what tolerance ranges apply to the application of the lubricant. Finally, it is not clear if this lubricant was accounted for in the cleaning and sterilization validation studies. Step 6.12 of PR3033 states, "Place the EndoWrist in the ultrasonic bath; refer to PR3036 In-Process U/S Cleaning SOP." Review of PR3036 does not clarify what part of the device is subjected to the cleaning or why this cleaning is performed. Again, it is not clear if these procedures have been accounted for in the cleaning validation studies. Please revise your protocol to clarify these issues, and provide an explanation of whether these lubrication steps have been included in your cleaning and sterilization validation studies. If this lubrication step was not included in your cleaning and sterilization validation studies, please repeat the validation studies to demonstrate that the presence of lubricant does not affect the ability to effectively clean and sterilize the device.
- d. Protocol PR3025, Scissors Sharpen and Refurbishment, states that TheraBand is inserted to remove burs from the cutting blades. However, it is not clear what TheraBand is. Please provide a comprehensive description of TheraBand, including its material composition.

- e. Protocol PR3050, Final Test, includes visual inspection along with a series of functional tests. However, it does not appear to include a final inspection for visible soil. Please revise the protocol to include a final visual inspection step before component reassembly to assess for any visible soil or other extraneous materials with defined acceptance criteria (e.g., “no visible soil”, etc.).
4. In Attachment C of Supplement 2, you provide a table describing the purpose, acceptance criteria, and product specifications for each procedure. However, it does not appear that the cleaning processes have adequate tolerances established. For example, the “Ultrasonic Cleaning & Flush” states a minimum power density of 48 watts/gallon, ultrasonic frequency of 38 kHz or greater, and solution temperature as close to 45°C. Please revise your remanufacturing procedures to have defined tolerance ranges with minimum, maximum, and nominal values for all applicable processes. Also, many of the acceptance criteria listed in Attachment C state that the device must pass a visual inspection. However, it is not clear what the actual pass/fail criteria are for these tests. Please revise Attachment C to explain what the acceptance criteria are for each visual inspection performed.
 5. Although you have provided reprocessing instructions to the user, it does not appear that you have provided any instructions on how to ship the used OEM device to you, including whether the user should reprocess the device before shipping or send the device dirty. We note that on page 42 of Module J it is stated, “...the end user is supposed to return equipment sterilized.” In addition, the labeling should state which devices are candidates for remanufacture. For example, devices must have one use life remaining, and only devices subjected to a validated list of reprocessing methods should be returned for remanufacturing. Please revise your labeling to include instructions on preparing devices for shipment and which devices are candidates for remanufacture.
 6. Numerous recalls for the Intuitive Surgical da Vinci EndoWrists have been identified in the FDA Recalls database (available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm>). Please examine all reports in the FDA Recalls database regarding the da Vinci EndoWrists, and provide a risk analysis to address the issues identified in these recalls. In your risk analysis, please address the risk mitigation measures you have in place for addressing the issues in each recall. Please provide a copy of your risk analysis in your response. In addition, please specifically address the following issues:
 - a. You provide a description of the remanufacturing process in Supplement 2, Attachment B. However, it is unclear if or how recalled devices are identified and rejected during the incoming evaluation phase of your remanufacturing process. Please clarify any methods by which recalled devices are identified and rejected as unacceptable candidates for remanufacture.
 - b. Numerous reports in the Recalls database (e.g., Z-0435-2015, Z-0439-2015, etc.) describe EndoWrist products that were recalled since “Deviations in reprocessing

steps from those stated in the reprocessing instructions can cause surface degradation of the housing and/or accelerate mechanical wear of the instrument.” These recalls underscore the importance of tracking the reprocessing history of all incoming devices (i.e., tracking how these devices were reprocessed by the previous end user prior to re-manufacture). Please see Deficiency 3b for more information regarding this matter.

- c. Several reports in the Recalls database (e.g., Z-1965-2014, Z-0258-2008, etc.) describe products that were recalled due to incorrect labeling (e.g., either on the device housing or in the User Manual). These recalls led to changes to the device labeling. Please describe any methods you have in place for tracking changes to the OEM labeling and incorporating these changes into the subject device labeling.
- d. Several reports in the Recalls database (e.g., Z-0520-2014, Z1442-2013, etc.) describe products that were recalled due to potential for device failure (e.g., potential for jaw detachment or device cracks, etc.). These “potential failures” may not be evident in new devices; rather, the probability of these failures increases over the course of the device’s lifetime as the number of uses increases. Please identify any methods you have in place for identifying and mitigating the risk of these potential device failures following remanufacture of your subject devices.

Labeling

The following deficiencies refer to the proposed labeling you have provided, and include general labeling concerns along with concerns regarding your proposed reprocessing instructions. Please refer to “Device Labeling” (available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/DeviceLabeling/ucm2005422.htm>) for general labeling concerns, and the guidance document, “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff” (available at <http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf>), for concerns regarding reprocessing information.

7. You provide the Instructions for Use (IFU) for the subject device through email on May 22, 2015. However, the Indications for Use in the subject IFU differs slightly from the Indications for Use in the 510(k) Summary and the Indications for Use Form. The following sentence is omitted from the Indications for Use in the subject IFU, but is present in the 510(k) Summary and Indications for Use Form:

“The Instrument is for use only with the Intuitive da Vinci S and da Vinci Si Systems (Endoscopic Instrument Control System).”

Please revise the Indications for Use so that it is identical across the labeling, 510(k) Summary, and Indications for Use Form and provide a copy of the revised documents in your response.

8. Protocol PR3027, Housing Labeling, states that Rebotix branding will be laser engraved onto the housing of all remanufactured instruments. However, you have not provided any images of how the engraving will appear. Please provide images of all laser engravings that will be added to the device housing. Please also see related Deficiency 11c below.
9. In the cleared predicate IFU in K063220, the following contraindication is listed as a general contraindication for all EndoWrist devices:

“This instrument may only be used on soft tissue. Do not use it on cartilage, bone or hard objects. Doing so may damage the instrument and make it impossible to remove it from the cannula.”

However, in the subject IFU, this contraindication is only listed for the PK Dissecting Forceps. Please provide a rationale for why this contraindication is only listed for the PK Dissecting Forceps in the subject IFU and not the other device models. Alternatively, please revise the subject IFU so that this contraindication is listed for all EndoWrist devices. Please provide a copy of your revised labeling in your response.

10. The following warning was removed from the subject IFU with respect to the cleared predicate IFU in K063220:

“Do not remove the cannula and [EndoWrist] instrument simultaneously as this may damage the surrounding tissues and the instrument.”

Since this warning was present in the predicate IFU, please provide a rationale for why it was removed. Alternatively, please add this warning back to the subject IFU, and provide a copy of your revised labeling in your response.

11. You provide the IFU for the subject device through email on May 22, 2015. You state that the IFU was formatted to “...align with the content organization of the OEM IFU.” However, the differences identified below were noted between your subject IFU and the OEM IFU. Please provide revised labeling to address these concerns.

- a. Unlike the OEM IFU, the subject IFU does not contain a Table of Contents. Due to the large quantity of information present in the subject IFU, we recommend you to include a Table of Contents in the subject IFU so that the end user can readily access important information.
- b. Page 13 of the OEM IFU contains safety and compatibility information regarding the EndoWrist ProGrasp Forceps. This information includes a list of devices that can be used safely with the ProGrasp Forceps. However, this information is not included in the subject IFU. Since the subject device includes Remanufactured ProGrasp Forceps, please add this information to the subject IFU so that the user can understand how to safely use the Remanufactured ProGrasp Forceps.

- c. Page 4 of the subject IFU states, “The remanufactured EndoWrist instruments have a blue housing with the instrument description. They also have the da Vinci S logo prominently displayed on the housing.” However, unlike the OEM IFU, a picture of the device housing is not provided in the subject IFU. Furthermore, in Attachment B of Supplement 2, you state, “‘Remanufactured By,’ the Rebotix Logo, and ‘Not Affiliated with Original Manufacturer’ are added to the Instrument housing.” However, this information is not mentioned in the device housing description provided in the subject IFU. In order to help the user distinguish between remanufactured devices and OEM EndoWrist devices, please provide a picture and description of the Remanufactured device housing in the subject IFU.
- d. Page 21 of the OEM IFU contains a list of electrosurgical units (ESUs) and energy activation cables that can be used with the subject device, along with the following associated notes regarding use of the EndoWrist instruments:
 - i. “Note: Not all da Vinci and da Vinci S surgical systems are equipped with a bipolar connection and will not be compatible with the above bipolar energy activation cables. Contact your local Intuitive Surgical representative to confirm your system’s configuration.”
 - ii. “Note: The da Vinci S and Si instruments have been evaluated for use only with the above ESU generators, and are compatible only with interconnecting cords and ESU generators that are in compliance with IEC 60601-2-2: 1998, IEC 60601-2-2: 2006, or IEC 60601-2-2: 2009.”

However, this information is not included in the subject IFU. Please note that you provide instructions regarding specific ESUs (e.g., Covidien Force FX-C, ConMed 5000, etc.) in the subject IFU, and this information may appear out of context to the user since a list of compatible ESUs and cables is not provided. Since knowledge of compatible ESUs and cables is necessary for safe and proper use of the subject device, please provide a list of ESUs and energy activation cables that can be used with the subject device, along with their associated warnings.

- e. Page 37 of the OEM IFU contains instructions and figures regarding proper installation of the Tip Cover Accessory on the Monopolar Curved Scissors. While the subject IFU contains most of these instructions, it omits the following instruction along with the corresponding figure illustrating this instruction:

“[The Tip Cover Accessory] is not properly installed beyond the orange surface and over the shaft. This causes a bulge on the shaft and may prevent it fitting through the cannula.”

Since this information is essential to safe use of the Monopolar Curved Scissors, please add this instruction to the subject IFU, along with a corresponding figure illustrating this instruction.

- f. The following instructions regarding energy activation cables are present in the OEM Manual:
 - i. “Note: Energy activation cables are non-sterile and do not require sterilization before use.” (page 20 of OEM IFU)
 - ii. Cleaning and Storage instructions regarding use of the energy activation cable (pages 31 – 32 of OEM IFU)

It appears you may have chosen to omit these instructions since energy activation cables do not appear to be part of the subject device. Nonetheless, proper handling of the activation cable is necessary for proper functioning of the subject device. As such, we recommend providing a statement in your IFU referring the user to the OEM IFU for instructions regarding the energy activation cables.

12. You provide the IFU for the subject device through email on May 22, 2015. This IFU contains the following sections:

- Section 1. General Information
- Section 2. Remanufactured EndoWrist Instruments
- Section 3. ESU Settings and Energy Activation Cables
- Section 4. Remanufactured Monopolar Curved Scissors
- Section 5. Remanufactured Permanent Cautery Instruments
- Section 6. Remanufactured Bipolar Instruments
- Section 7. Remanufactured PK Dissecting Forceps
- Section 8. Cleaning and Sterilization of Remanufactured EndoWrist Instruments

Several of these sections (e.g., Sections 2, 4, 5, 6, 7) include instructions for specific categories of devices. However, since a list of applicable device models is not provided for each section, it is not readily apparent which sections apply to each device model. For example, Section 6 provides instructions for the Remanufactured Bipolar Instruments, but a list of bipolar device models is not provided. Furthermore, it is unclear which sections of the IFU apply to non-energized device models, since the IFU does not include a specific section on remanufactured non-energized devices. It is also unclear if Section 2 only applies to non-energized devices, or if it applies to all EndoWrist models. Please provide a list of applicable device models for each section 2, 4, 5, 6, and 7, so that the user can clearly understand how to use each device model. Please provide a revised copy of your labeling in your response.

13. On pages 1 – 50 of Module D, you provide package labels for the subject device. The symbols utilized in these package labels are defined in the IFU, but not defined in the package labels. Please note that the FDA does not recognize any standalone symbols

except for the “Rx only” symbol. Therefore, please revise your package labels to include textual descriptions for these symbols, placing this description near each symbol as it appears in the labels. Please note that any definitions for symbols used on the package label should be present on the package label and not in the IFU. Please provide a copy of your revised labeling with your response.

For more information on the recognition of symbols in labeling, please see the proposed rule that was issued in the Federal Register on April 19, 2013. This proposed rule may be found online at <http://www.gpo.gov/fdsys/pkg/FR-2013-04-19/html/2013-09175.htm>.

14. In your email dated May 22, 2015, you provide an IFU for the subject device that includes reprocessing instructions for the end user. In general, it appears that the instructions follow FDA’s Guidance Document “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling” issued on March 17, 2015, with the following exceptions noted. Please revise your reprocessing instructions as described below, and provide a clean and redlined (tracked changes) copy of the revised IFU with your response.
 - a. Page 6 states, “Clean the instruments immediately after each use. Do not allow debris to dry on or inside the instrument intraoperatively *before* instrument processing. In order to keep the instrument from drying when soiled, keep the instrument in water or an enzymatic bath between the surgical procedure and instrument processing. The instrument may also be flushed through the main flush port with sterile water during use to minimize buildup of internal deposits of bio-material.” However, it is not clear if these instructions have been validated, in terms of the number of use lives, based on performance or appearance of corrosion, etc. It is recommended that you revise the instructions in accordance with your validation activities. Please also revise the wording, “water” and “enzymatic bath,” to clarify the quality of water and pH of cleaning agent that should be used.
 - b. Page 24 states, “The PK Instrument Cords are reusable for a maximum of twenty (20) reuse cycles. Mark the usage tracker on the cord label after each use.” If the PK Instrument Cords are not considered part of your submission, please revise the labeling to recommend that the user refer to the OEM labeling for these cables. If they are part of your submission, additional reprocessing instructions should be provided for the PK instrument cord. Please include reprocessing instructions for the end user and also provide a description and image of the usage tracker. Finally, please explain if the tracking marks are able to be removed by reprocessing and whether any special instructions should be provided on what type of marker should be used to mark the usage tracker.
 - c. Page 25 contains the following statements that are not adequate in relation to the manufacturer’s responsibility to provide validated reprocessing instructions to the user. Please note that validation of the reprocessing instructions is the responsibility of the device manufacturer and not the end user (see Section VII of

the above referenced Reprocessing Guidance). Therefore, please remove the following statements from your labeling:

- i. “Cleaning, disinfection, and sterilization of reusable devices are the responsibility of the hospital or site performing the process.”
 - ii. “These steps may need to be adjusted or repeated depending on soiling conditions or specific cleaning equipment used.”
- d. Page 25 mentions “endoscopes” in the statement, “The process and parameters listed are recommendations for cleaning, disinfecting, and sterilizing the remanufactured EndoWrist instruments, accessories, and endoscopes and have been validated...” However, endoscopes are not included in your current submission. Therefore, please remove this reference to endoscopes from your IFU. In addition, your reprocessing instructions do not appear to include disinfection; therefore, please also remove the reference to “disinfecting” in the referenced statement.
- e. Page 25 states, “Examine the device before and after each use. If any abnormality is found, do not use the device.” Please revise these instructions to include a description of an “abnormality.”
- f. Page 25 states, “Note: If Electro Lube anti-charring solution for cautery instruments is improperly applied, those instruments may require additional scrubbing and high-pressure water spray.” It is not clear what instructions this note applies to, since the use of Electro-Lube does not appear in the remainder of your reprocessing instructions. The referenced note also does not describe how to properly apply the lubricant or how the user can know the lubricant is “improperly applied.” Furthermore, the Electro-Lube lubricant is not mentioned in the predicate reprocessing instructions. Finally, it does not appear that the referenced note or the general use of Electro-Lube lubricant have been accounted for as part of your “worst case” reprocessing validation protocol design. Please also note that the lubricant manufacturer (Mectra Labs, Inc.) received a warning letter from the FDA on November 14, 2013 warning them that there is no approved pre-market approval application for the Electro-Lube product for the intended use with robotic instruments (<http://www.fda.gov/iceci/enforcementactions/warningletters/2013/ucm375446.htm>). For these reasons, it is recommended that you remove all references to Electro-Lube lubricant from your labeling.
- g. Page 25 states, “Note: Remanufactured EndoWrist instruments have not been validated for compatibility with the optional thermal disinfection cycle on the Medisafe SI PCF system.” However, thermal disinfection does not appear to be a step in your reprocessing instructions, and the Medisafe SI PCF is not cleared for the intended use mentioned in your IFU. Therefore, please remove this note from your labeling.

- h. Your instructions include temperature ranges and minimum exposure times for your steam sterilization parameters, rather than discrete times and temperatures. For example, page 27 lists the pre-vacuum steam sterilization temperature as “270-272°F (132-134°C)” and lists a “Minimum exposure time for the U.S.: 4 min.” Page 27 also includes the warning “Do not sterilize at temperatures over 285°F or 140°C.” Please note that the Reprocessing Guidance states “FDA recommends that ‘ranges’ not be used for defining sterilization cycles (for example, 121°C-132°C and greater or lesser than 4 minutes exposure time), as this implies that all intermediate values have been validated, and that there are FDA-cleared accessories for all intermediate cycles.” Please revise your sterilization instructions to include one discrete temperature and exposure time, in accordance with your validation activities. Please note that FDA recommends that steam sterilization cycle parameters be consistent with those listed in Appendix C of the Reprocessing Guidance and ANSI/AAMI ST79:2010 & A1:2010, “Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.”
- i. Your instructions include multiple Flush and Rinse steps. Please revise the instructions to include the type/quality and temperature of rinse water to be used in these steps, in accordance with your validation activities. Please note that AAMI TIR34, “Water for the Reprocessing of Medical Devices,” recommends that the final rinse water for devices that will contact sterile areas of the body, such as the subject device, use critical water. For “Step 6: Rinse” on page 27, please also revise your instructions to include the duration of rinse and, in particular, how long the user should “...rinse into the area where the instrument shaft enters the housing.”
- j. “Step 1: Scrub” on page 26 states, “Repeat scrubbing as needed.” It is recommended that you revise this statement to specify how the end user is to know that repeated scrubbing is necessary.
- k. “Step 8: Lubricate” on page 27 states, “Lubricate the tip and wrist mechanism with a pH-neutral, steam-permeable instrument lubricant per the manufacturer’s instructions.” Please revise these instructions to include the general type of lubricant the user should use, in accordance with your cleaning and sterilization validation studies (e.g., “water soluble lubricant”). Otherwise, please remove this instruction from the labeling if it has not been validated.
- l. It does not appear that your instructions include the number of reuse lives that are validated for each of the device models. FDA is aware that your devices include an Interceptor chip for tracking the number of device uses. However, it may be useful to the end user to include in your Reprocessing Instructions how many times the reusable devices can be reused and a description of the chip tracking mechanism.

- m. Your instructions list multiple accessories (e.g., syringe, soft nylon brush) that do not include adequate descriptions such as size/diameter and type of syringe (e.g., Luer). The instructions also list pressure specifications for flushing the flush ports with pressurized water (i.e., “minimum of 30 psi”), but it is not clear how the pressurized water should be introduced into the flush port (e.g., is a type of Luer fitting or other accessory to be used?). Furthermore, it is not clear if you provide these accessories with the device or if the user needs to purchase these supplies themselves. Please revise your instructions to include a complete description of all cleaning accessories and how the user is to obtain these items. Please also include comprehensive instructions on how the user should introduce the pressurized water into the flush ports. Including images of these steps and accessories may be helpful to the user.

Cleaning Validation

The following deficiencies refer to the cleaning validation activities that you have proposed as part of your remanufacturing process and that you are recommending to users in the reprocessing instructions. Please refer to the guidance document, “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff” (available at <http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf>), for additional information.

15. In Attachments B and C of Module E, you provide your justification for the “worst case” device models chosen for cleaning validation (i.e., the Monopolar Curved Scissors, Permanent Cautery Spatula, Fenestrated Bipolar Forceps, PK Dissecting Forceps, Large Needle Driver, and ProGrasp Forceps). Your “worst case” analysis outlines a brief description of the tool end design, materials, surface area, and worst case conclusion based on “risk.” It appears that the analysis included consideration of the design configuration, number of components, materials of construction, size and density, surface area and porosity, need for disassembly, surface finish or texture, cannulations or lumens, presence of mated surfaces, and ability to be sterilized in a routine cycle. However, your analysis is not sufficient to determine if your justification for the chosen “worst case” models is appropriate in terms of cleaning validation and difficulty of cleaning the device over other models. Please repeat the analysis by including parameters such as the following: instruments that would collect the highest amount of soil in the inner shaft and on the tip, hardest to reach areas to remove soil, smallest spaces between components, and lowest flushing efficiency (e.g., number of cables in the inner shaft, distance between the distal seal and the termination of the flush tube). If any new “worst case” models are identified due to the new analysis, please provide results from cleaning validation performed using these additional models.
16. You provided “Medisafe Cleaning Process Validation” test reports in Attachments E-4 and E-5 of the original submission for analysis of residual protein and total organic carbon (TOC), respectively. It appears that the Medisafe PCF system and the Medisafe 3 E-zyne Triple Enzyme Cleaner were used in the testing. However, it is not clear why

these reports are provided since no automated washer-disinfector, including the Medisafe PCF system is mentioned in your reprocessing instructions. In addition, as noted in the related Deficiency 14g, the Medisafe is not cleared for this intended use. Please explain the purpose of these test reports provided in Attachments E-4 and E-5.

17. On page 7 of Module E, you state that you have utilized 48 test samples (8 of each of the worst case models) in your cleaning validation studies. However, from Table 2 in the cleaning validation test reports, it appears that 18 samples were used in the tests. From Table 2, it also does not appear that each worst case device model was used in each of the three test cycles. It further appears that the control device models did not match the test sample device models. Finally, it is not clear how many and what type of samples were used for the cleaning efficacy study versus the extraction/recovery efficiency study. Please note that FDA expects all worst case device models to be tested in all cleaning cycles and matched with the same model for all controls. In addition, FDA expects the following controls to be included in the study:
 - a. Negative device controls should be unsoiled and undergo the same cleaning and extraction as the test devices; the amount of residual soil should be at or slightly above the negative control.
 - b. Positive device controls should be soiled with a known amount of soil, but not cleaned, and residual soil extracted; the amount of residual soil should be equivalent to or slightly lower than the amount of soil placed. Soil recovery efficiencies should be calculated and used during the calculations.
 - c. Negative sample control in which “extraction” is conducted with no device. This sample is used as a blank.
 - d. Positive sample control in which a known amount of soil (at or slightly above the limit of quantitation) is added to an “extraction” with no device; this control addresses interference of the extraction fluid and extraction method with soil detection.

Please repeat your cleaning validation study with all worst case device models and using appropriate controls. Please also provide a statistical rationale for the sample size chosen in your cleaning validation studies.

18. Your cleaning validation protocol did not explain how the devices were selected for the study. Please revise your protocol to explain how the devices were selected for the study, including their clinical use, remanufacturing and reprocessing. FDA’s expectation would be that the devices used in your study are clinically used devices that were found to have worst case native soiling based on your conduction of a Native soil Characterization Study (see below for more information on this suggested study). Please also explain how the clinically used devices were reprocessed, since changes in the OEM’s reprocessing instructions could be implemented differently at the health care facilities and have a

significant effect on the validated use lives. Please repeat your cleaning validation study taking into account these issues, and provide detailed methods in your revised test report.

19. Your cleaning validation protocols state that "...the artificial test soil used to inoculate the devices mimicked worst case contaminants (blood and proteins that may come in contact with the devices and remain on the devices after clinical use)." The test devices were soiled using the artificial test soil in order to obtain an average minimum protein level of $115 \mu\text{g}/\text{cm}^2$ and an average minimum TOC level of $39.1 \mu\text{g}/\text{cm}^2$ over the soiled surface area of the devices. You further state that "...this protein level is based on study data which quantified worst case soil levels of medical instruments after patient use (Alfa et al., 1999)," and that the "...TOC level is based on a study which quantified worst case soil levels of medical instruments after patient use (Lappalainen, SK; Gomatam SV; and Hichins V. Residual total protein and total organic carbon levels on reprocessed gastrointestinal (GI) biopsy forceps. J Biomed Mater Res B Appl Biomater 89B:172-176, 2009)."

Please perform a Native Soil Characterization Study to investigate the amount of soiling present on clinically used EndoWrist devices to determine that the soil constituents and amount of soil are indeed worst case compared to what would be expected clinically. The study should include a quantitative scale to evaluate native soil as well as images of all soiled surfaces (including internal components). It is recommended that only worst case natively soiled devices be used in your cleaning and sterilization validation studies, and that this information then be used to develop your incoming device acceptance criteria. If worst case natively soiled devices were not used in your cleaning and sterilization validation studies, please repeat the studies using worst case soiled devices. Please provide the completely study protocols and reports for the Native Soil Characterization Study and any repeated validation studies with your response.

20. In Figure 1 of your cleaning validation test reports, you provide an image of the device soiling locations. However, the image is not legible. The caption, which is legible, states that the tip of the device was dipped into soil to point A (which appears to be just above the wrist of the instrument) and actuated to the full range of motion. It further states that a lumen cleaning brush was dipped into soil and then threaded into the main flush ports as far as possible. From this limited description, the test soil does not appear to be applied to the devices in a "worst case" simulated use manner, since it did not include injection of artificial soil into inner lumens, handling with soiled and gloved hands, or inoculation of the outer shaft, which would be expected to be soiled by user handling. Please revise your test reports to provide clearer images of all soiling and a comprehensive description of soil inoculation. Please also repeat the cleaning validation with worst case soiling of the device. It may be necessary to extract different parts of the device separately (e.g., tip vs. inner lumen) and calculate the results separately, since the extraction methods may differ, and since including the surface areas of each device component may lead to lowering the calculated residual soil per surface area. For example, including the higher surface areas of the outer shaft that is easier to clean with the harder-to-clean areas may negatively impact the results. Please provide the complete protocol and test reports of any repeated testing with your response, including raw data generated.

21. Your cleaning validation protocols do not appear to include simulated use of the instruments. For the electrosurgical devices, this is especially important since the soil can be baked onto the device, making it harder to clean. Please repeat your cleaning validation studies using devices that were subjected to a series of simulated use and “worst case” reprocessing (i.e., minimum conditions) over the proposed number of use lives at the health care facility, as well as any additional remanufacturing/reprocessing performed at your facility. With your response, please provide a detailed protocol of the methods used for simulated use, along with complete test reports with raw data.
22. In Table 1 of your cleaning validation test reports, you provide the surface area of the device models used in your cleaning validation studies. However, it is not clear how these surface areas were calculated, and which part of the devices were included in the calculation. You state in the Discussion section of the test reports, “Due to large amounts of the Da Vinci Endowrist surface area not making patient contact, only the surface areas of the device that would come in contact with the soil were used in the calculations...[for residual soil].” However, it is not clear what is classified as the patient vs. non-patient contacting portions of the device. In addition, please note that certain non-patient contacting parts of the device may become soiled from user handling. It should also be noted that if the interior of the device is soiled (e.g., the lumen or flush ports), the internal surface area of that device component should be used in the calculations. Please provide a comprehensive description of the surface area calculation and determination of soiled areas. It may be helpful to provide images with your explanation.
23. Your cleaning validation protocols state that the inoculated test samples and positive controls were allowed to dry at room temperature for a minimum of two hours to simulate worst case conditions. Although this treatment appears to be worst case compared to that specified in the Reprocessing Instructions (which state to clean the device “immediately after procedure” and “keep the device in water or an enzymatic bath between the surgical procedure and reprocessing”), it is not clear how this timeframe would be considered “worst case” for the timeframe of soiled instruments being shipped from the health care facility to the Rebotix facility. Please clarify how this timeframe is considered “worst case” with respect to soiled instruments being shipped to the Rebotix facility. If applicable, please provide repeat cleaning validation to reflect a revised “worst case” timeframe with respect to soiled instruments being shipped to the Rebotix facility.
24. Your cleaning validation test reports state, “Worst case cleaning procedures and conditions were used throughout the validation. For example, cleaners and detergents were prepared according to the manufacturer’s instructions using the lowest range of concentration recommended (minimum effective concentration). The least effective (lowest) cleaning temperatures, within recommendations, were used for the rinsing and cleaning steps.” The cleaning procedures used in your cleaning validation study were compared to the proposed reprocessing instructions, as well as your remanufacturing procedures. However, key details are missing, such that we are unable to determine if “worst case” conditions were used in your validation studies over those specified in your reprocessing instructions and in your remanufacturing procedures. Please provide a

tabular comparison of the cleaning parameters used in their cleaning validation study versus those in the reprocessing instructions and remanufacturing procedures, in order to demonstrate that “worst case” parameters were used in your cleaning validation studies. The comparison should include all relevant cleaning parameters, such as water quality, water pressure, time, temperatures, concentrations, any repeated scrub/rinse steps, detergent type, lubricants, ultrasonic cleaning parameters, etc.

In addition, please provide an explanation of the worst case temperature conditions used for the cleaning agents used in your cleaning validation studies. For example, your protocol states that you used an enzymatic detergent solution of Steris Prolystica 2X Concentrate Enzymatic Cleaner prepared at the lowest recommended concentration of detergent (1/8 oz. per gallon) and temperature (cold water). However, you have not provided information to demonstrate that “cold water” is considered worst case for this cleaning agent nor have you defined “cold water.” Please provide a definition of “cold water” along with your explanation of worst case temperature conditions for the cleaning agents used in your cleaning validation studies.

25. It does not appear that the cleaning methods used in your cleaning validation protocols included a lubrication step, which is recommended in your reprocessing instructions, and which appear as part of your remanufacturing procedures. However, it is noted that page 43 (Attachment E: Parts and Materials) of Module E, Sterilization, from your original submission lists “Steris Hinge Free Lubricant.” Since there is no further explanation provided with Attachment E, it is not clear what the purpose of this lubricant is, or whether it was included in the cleaning validation studies. Attachment E also lists “Ruhof Surgistain Rust Remover” and many other unknown materials. Please provide a comprehensive explanation of each of these materials and a flow chart of how the device is treated or used with each. Finally, please repeat your cleaning validation studies to ensure that all treatments the device is subjected to during your remanufacturing procedures, or will be subjected to by end-user reprocessing, are accounted for in your studies.
26. From Section 3.0 “Equipment and Materials” of your test reports, it appears that the extraction fluid used in your cleaning validation studies was distilled water, but there is no description of the extraction container. The Agency is concerned that using water as an extraction medium would not adequately extract residual soil from the surface of a complicated device such as the subject device. For example, the tip and lumen contain multiple coiled wires that could trap soil and be difficult to extract. It is suggested that you consider using a surfactant, such as sodium dodecyl sulfate, as an extraction medium, provided that it does not interfere with your endpoint assays. It appears that you have used an exhaustive extraction method for calculating recovery efficiency; however, it is not clear if this method is adequate for this complicated device, especially if the soil is not easily removed by the extraction medium. It also does not appear that your extraction method allows for sampling of the internal structures of the device (e.g., inside the flush ports and tubes and internal lumen).

Please repeat your cleaning validation studies using an extraction method that can adequately extract all complex internal structures that are exposed to soil. Please also perform an additional test to (1) validate your extraction methods by inoculating a known amount of soil in the hardest to reach areas of the device at a low volume/dilute amount below the endpoint acceptance criterion, (2) extract and quantify the soil, and (3) determine how much soil was able to be removed from the device. Finally, please revise all test reports to include a description of the extraction container, extraction temperature, and extraction volume (and device surface area to extraction volume ratio) used in your cleaning validation studies, as well as the raw results for the extraction/recovery efficiency study, including the number of extractions performed in the exhaustive recovery and calculation of the correction factors. It is recommended that the surface area to extraction volume ratios listed in ISO 10993-12:2012 be used in your studies or that you provide a rationale for other ratios used.

27. From the “Equipment and Materials” list in your cleaning validation test reports, it appears that the assay used to detect residual protein was the MicroBCA assay, and that the Hach Reagent Kit and “DRB reactor” were used to detect total organic carbon (TOC). However, you have not provided the assay methods, mechanism of action for detection, the limit of detection, limit of quantitation, or characterization of any interfering substances for either assay. Please revise your cleaning validation test protocols and reports to include this information.
28. In Step 5.15 of your cleaning validation protocol, you state that “...the test samples were visually inspected to ensure the complete removal of soil.” However, it is not clear if visual inspection for visible soil was an explicit acceptance criterion for your studies, or what the results of visual inspection were for the test samples and positive and negative controls. Since the subject device has a complicated design that can make cleaning difficult, it is recommended that you use methods to visually inspect all soiled areas of the device, including internal surfaces. To assess whether any visible soil remains on the internal surfaces, it may be possible to use a borescope. It is also recommended to use microscopic visualization of debris on all areas where it is possible to do so. Please repeat your cleaning validation studies, as applicable, to generate this data, and revise all of your cleaning validation protocols and test reports to include your visual inspection acceptance criteria and results.
29. In your cleaning validation test reports, you provide tables to summarize the data for each cleaning cycle. However, no results are provided for several of the test cycles for each assay test method, with no explanation for this missing data. Please revise your test reports to include data for each cleaning cycle to demonstrate reproducibility, and please also explain whether any deviations or failures occurred in any of the cleaning validation testing. In addition, please revise your test reports to include both the corrected (based on % recovery efficiency and related correction factor) and uncorrected raw data from your cleaning validation studies.
30. In the discussion section of your TOC cleaning validation test reports, you provide the following note: “Due to the elevated TOC levels of the negative controls, a baseline

TOC level was used by subtracting the negative control TOC values from the test sample and positive control TOC values. This was done to assure that measurement of the effectiveness of the cleaning process was based only on the reductions in the TOC levels contributed by the test soil applied to the challenged devices and not from interfering substances such as residual detergent or leaching chemicals. After applying the baseline TOC level, all test samples met the acceptance criteria.” However, the TOC results from your negative controls are not adequate; neither is the subtraction of these results from the test samples and positive control results. The Agency considers this an inappropriate adjustment of the data and, therefore, it appears that the negative controls and test samples do not meet the acceptance criterion of $< 2.2 \mu\text{g}/\text{cm}^2$ for TOC. It appears that the TOC endpoint assay used in your studies may not be appropriate, or there may be interfering substances present. Please revise your cleaning validation methods to obtain acceptable results that meet at least two quantitative acceptance criteria for residual soil.

Sterilization Validation

The following deficiencies refer to the sterilization activities that you have proposed as part of your remanufacturing process and that you are recommending to users in the reprocessing instructions. Please refer to the guidance document, “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff” (available at <http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocument/ucm253010.pdf>), for additional information.

31. In Attachments B and C of Module E, you provide your justification for the “worst case” device models chosen for sterilization validation (i.e., the Monopolar Curved Scissors, Permanent Cautery Spatula, Fenestrated Bipolar Forceps, PK Dissecting Forceps, Large Needle Driver, and ProGrasp Forceps). Your “worst case” analysis outlines a brief description of the tool end design, materials, surface area, and worst case conclusion based on “risk.” It appears that the analysis included consideration of the design configuration, number of components, materials of construction, size and density, surface area and porosity, need for disassembly, surface finish or texture, cannulations or lumens, presence of mated surfaces, and ability to be sterilized in a routine cycle. However, your analysis is not sufficient to determine if your justification for the chosen “worst case” models is appropriate in terms of sterilization validation and difficulty of sterilizing the device over other models. Please repeat the analysis by including parameters such as the following: hard to reach spaces that do not allow for easy steam access, presence of any additional cables that provide crowding for most difficult to reach small spaces and most difficult air removal from the internal shaft, and interfaces of different materials that affect moisture elimination. If any new “worst case” models are identified due to the new analysis, please provide results from sterilization validation performed using these additional models.
32. You provided a sterilization efficacy report in Attachment E-6 of the original submission. However, the following items identified in the test report require additional information:

- a. You state in Section 5.0, Validation of Spores, of the test report, “The D-value was no less than 1.0 minute and the population no less than 1.0×10^6 .” However, the biological indicator (BI) does not appear to comply with ISO 11138-3: 2006, “Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat sterilization processes.” Clause 9.5 of the standard states, “Suspensions, inoculated carriers or biological indicators containing *Geobacillus stearothermophilus* spores shall have a D_{121} value of ≥ 1.5 minutes when tested according to the conditions given in Annex A.” Please repeat the sterilization validation using an appropriate BI. In addition, please provide the actual results from the BI validation results since they are not provided in the test report.
- b. It appears from your sterilization validation report that the devices were placed into pouches (i.e., “SPSmedical Self-Seal Pouches”) and not a sterilization wrap, as recommended in the reprocessing instructions. Please either revise your reprocessing instructions to recommend that an FDA-cleared sterilization pouch be used (in accordance with your sterilization validation study), or provide results from sterilization validation using an FDA-cleared sterilization wrap.
- c. Section 7.12 of the test report states that “positive and negative controls were set up”; however, there is no description of the test methods used for the various controls. Please revise the test report to include comprehensive methods for what the controls entailed and how the controls were handled.
- d. You perform a “Negative Verification Test” using samples inoculated with ≤ 100 spores of *Geobacillus stearothermophilus* and “incubated per USP.” The test methods are not entirely clear, and it does not appear that the recommendations in USP <71> “Sterility Tests” were followed. USP <71> states to use a variety of microbes that include aerobic bacteria (*Staphylococcus aureus*, *Bacillus subtilis*, *Pseudomonas aeruginosa*), anaerobic bacterium (*Clostridium sporogenes*), and fungi (*Candida albicans* and *Aspergillus brasiliensis* (*Aspergillus Niger*)). Please repeat the “Negative Verification Test” using the test methods outlined in USP <71>, and provide a complete description of your test methods in your test report.
- e. Your test report does not state how the devices (test samples and controls) were treated prior to the sterilization validation study. Please revise your test report to include this information. Please ensure that all devices used in your sterilization validation studies included all steps in your remanufacturing procedures and all steps in your reprocessing instructions up to the sterilization instruction. For example, it is not evident that “Step 8: Lubricate” in your reprocessing instructions has been validated. Please repeat your sterilization validation, if necessary, to validate all steps in your reprocessing instructions. Please ensure that you have used proper controls in your study to account for the presence of lubricant and potential false negative results.

- f. It does not appear that you have validated the drying time for the steam sterilization method recommended in your reprocessing instructions. Please perform a sterilization validation study to validate the drying time by evaluating the dryness of the product by mass change and perceptible moisture, as described in ISO 17665-1:2006, “Sterilization of health care products—Moist heat—Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.”
- g. It does not appear that you have provided the results from bioburden enumeration and resistance or a description of your routine bioburden monitoring with action/alert limits. Please perform and provide results, including % recovery efficiency and recorded colony forming units per device, from a bioburden validation study in which the bioburden is enumerated on heavily soiled, clinically used devices after exposure to minimum cleaning parameters. Please also develop methods and alert limits for routine bioburden monitoring, and provide a description of these methods and alert limits with your response. Finally, please perform a bioburden resistance study using a fractional sterilization cycle to confirm that natural bioburden contained on the reprocessed device is less resistant than the biological indicators used in the sterilization validation and those used for routine cycle monitoring. Please reference and cite applicable standards where appropriate (e.g., ISO 11737-1:2006 (R)2011, “Sterilization of health care products—Microbiological methods—Part 1: Determination of the population of microorganisms on product”).

Biocompatibility

The following deficiencies refer to the biocompatibility testing that you have conducted to validate your remanufacturing process. Please refer to the Blue Book Memorandum #G95-1, “Use of International Standard ISO-10993, ‘Biological Evaluation of Medical Devices Part 1: Evaluation and Testing’” (available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080735.htm>), for additional information.

- 33. On page 2 of Module G, you state that the Remanufactured Fenestrated Bipolar Forceps and Remanufactured Monopolar Curved Scissors were selected as the two representative device models for Biocompatibility testing. Through email on May 15, 2015, you state:

“Each device did not contain all patient-contacting materials, but full coverage of added or modified material for all models was achieved by testing both of them. The table below outlines which materials are represented by each device tested. It should be noted that the ceramic heat sink that is present on the hook of one device model (420183) and spatula of another (420184) is never modified (polished or otherwise) or replaced during the remanufacturing process. As such, this component was judged not to pose any biocompatibility risk, as the stable ceramic material was clearly qualified as biocompatible as part of the OEM device, and is not later modified.”

However, we do not agree with your rationale that the ceramic heat sink does not pose any biocompatibility risk. Although you claim that the ceramic heat sink is "...never modified (polished or otherwise) or replaced during the remanufacturing process," the heat sink is reprocessed multiple times throughout the lifetime of the device. Due to the harsh nature of reprocessing agents, repeated reprocessing and use cycles may cause the ceramic to degrade or exhibit other adverse effects over the course of the device's lifetime. In addition, an aspect of the biocompatibility testing for a reusable device is to evaluate residual cleaning agents used during reprocessing.

Therefore, please perform testing on either the Remanufactured Permanent Cautery Hook (420183) or Remanufactured Permanent Cautery Spatula (420184) to demonstrate the biocompatibility of the ceramic heat sink. As noted in Deficiency 35 below, this testing should be performed at the end of the remanufactured device's use life (i.e., after being subjected to all remanufacturing procedures performed under worst case conditions, followed by worst case reprocessing for at least 11 cycles). In your response, please provide a complete description of the methods used to prepare the test samples prior to biocompatibility testing. Please also provide the full biocompatibility test reports for these devices, including a description of the test article, methods, pass/fail criteria, and results for each completed test.

34. The list of "Parts and Materials" on page 43 of Module E, Sterilization, lists "Steris Hinge Free Lubricant." As also stated in Deficiency 25, there is no further explanation provided with Attachment E; therefore, it is not clear how this lubricant is used or if it is applied onto a patient-contacting portion of the subject device. Please clarify if this lubricant is used on any patient-contacting portions of the subject device, and clarify if this lubricant is present on the devices used in your biocompatibility testing.

Furthermore, it appears that the Steris Hinge Free lubricant contains dimethylol-5,5-dimethylhydantoin (DMDMH), an antimicrobial preservative agent that is a formaldehyde releaser. If this lubricant is used on your subject device, please provide an MSDS and toxicology information to demonstrate the safety of this antimicrobial-containing lubricant. FDA is concerned that the presence of this antimicrobial lubricant on a patient-contacting portion of the device may lead to transfer of the lubricant to the surgical site where it could be in contact with tissue for longer than the 24 hours used to establish your biocompatibility testing. In addition, the presence of DMDMH raises concerns about potential genotoxicity and carcinogenicity. Please individually assess each of the chemical components in the lubricant used on your device and provide a toxicological risk assessment in accordance with ISO 10993-17, "Biological evaluation of medical devices – Part 17: Methods for the establishment of allowable limits for leachable substances." Please provide a tolerable intake analysis based on: (1) published no observed adverse effect level, (2) lowest observed adverse effect, and (3) an adequate safety margin as specified in ISO 10993-17. This information is necessary to establish substantial equivalence, in terms of safety, to the predicate device.

35. Through email on May 15, 2015, you describe the selection and preparation of the Remanufactured Bipolar Forceps and Remanufactured Monopolar Curved Scissors for Biocompatibility testing. You state:

“Worst case devices chosen for biocompatibility testing were those devices that collectively contained all patient contacting materials that were added or modified by the remanufacturing process, and were exposed to all remanufacturing processes that would be relevant to any individual model.”

You further state, “Previously used, expired devices were chosen for the testing, meaning that the device had been reprocessed a minimum of 10 times by the end-user. The devices were then subjected to our remanufacturing process which includes 2 additional reprocessing cycles (scrub, flush, ultrasonically clean and autoclave) for a total of 12 reprocessing cycles.”

However, sufficient descriptive information is not provided for FDA to fully understand how the devices were prepared prior to biocompatibility testing. Although you provide a rationale for selecting the types of devices used for biocompatibility testing, you do not describe the criteria by which the individual test samples were selected for the study. Please explain how the test samples were selected for the study, and address the following items in your response:

- a. A description of the reprocessing of the test samples by the end user prior to biocompatibility testing is not provided. Please provide a description of the reprocessing steps used on the test samples by the previous end user. This information is requested since changes in the OEM’s reprocessing instructions could be implemented differently at the health care facilities and have a significant effect on the device’s validated number of use lives.
- b. The remanufacturing procedures in Attachment B of Supplement 2 describe the use of multiple agents (e.g., TheraBand, lubricants, rust remover etc.) that may contact patient-contacting portions of the subject device. Please clarify if the test samples were subjected to ALL of the remanufacturing procedures in Attachment B of Supplement 2, including all of the remanufacturing agents described therein. In your response, it would be helpful to provide a list of agents used during the remanufacturing process that contact patient-contacting portions of the subject device, and to describe any assurances for removing residuals from these agents remaining on the device after remanufacture. Please additionally see Deficiency 34 regarding use of the Steris Hinge-Free lubricant on the subject device.

Finally, according to your email on May 15, 2015, it appears that subject devices were tested for biocompatibility immediately following the remanufacturing process. It appears that the devices were not subjected to biocompatibility testing at the end of their remanufactured use life (i.e., after 11 additional cycles of worst case reprocessing.) Please be advised that the devices should be tested for biocompatibility after being

subjected to all of the remanufacturing procedures (following worst case tolerance parameters) in addition to worst case reprocessing for at least 11 cycles.

Therefore, in order to demonstrate that the subject device remains biocompatible throughout its entire use life, please perform biocompatibility testing on the remanufactured devices after at least 11 additional cycles of worst case reprocessing. In your response, please provide a complete description of the methods used to prepare the test samples prior to biocompatibility testing. Please also provide the full biocompatibility test reports for these devices, including description of the test article, methods, pass/fail criteria, and results for each completed test.

36. In Attachments G-9 and G-10 of Module G, you provide test reports for hemolysis testing on the Remanufactured Fenestrated Bipolar Forceps and Monopolar Curved Scissors. However, only extract testing was performed on these devices; direct contact testing was not performed. Please note that ASTM F756-08 states, "It is recommended that both tests (extract and direct contact) be performed unless the material application or contact time justifies the exclusion of one of the tests." Therefore, please perform direct contact testing on your subject devices, or provide a valid scientific rationale for why this testing is not needed.
37. In Module G, You provide biocompatibility test reports for the Remanufactured Fenestrated Bipolar Forceps and Monopolar Curved Scissors. However, the normal saline extracts for both devices were described as being pale red in color, turbid, and containing red flake particulates in the Irritation, Sensitization, and Acute Systemic Toxicity tests. Please provide evidence to demonstrate that the presence of color, turbidity, and particulates in the extracts are not indicative of problems with product manufacturing, and/or inappropriate extraction conditions that may invalidate the findings of the study. Information regarding the chemistry of the product may be helpful in your response.

Electromagnetic Compatibility (EMC) and Electrical Safety

The following deficiencies refer to the EMC and electrical safety testing that you have conducted to validate your remanufacturing process.

38. In Module I, EMC and Electrical Safety, it is stated that devices were cleaned and autoclaved a total of 11 times prior to testing, in accordance with the reprocessing instructions provided in Attachment F of Module I. Although the reprocessing instructions provided in Module I appear consistent with the reprocessing instructions provided to the user, it is not clear if worst case parameters were used to prepare the test samples (e.g., longest exposure times, highest chemical concentrations, and shortest rinse durations) in terms of the remanufacturing procedures, but also the simulation of reprocessing that the end user would perform. The instructions also do not include discrete temperatures and times for sterilization. Please repeat your EMC and electrical safety testing on end-of-life devices that were remanufactured and reprocessed under worst case conditions.

39. Although you provide a rationale for selecting the types of devices used for electrical safety testing, your electrical safety testing protocol does not explain how the individual test samples were selected for the study. Please revise your protocol to explain how the test samples were selected for the study, including their clinical use and reprocessing by the end user. This information is requested since changes in the OEM's reprocessing instructions could be implemented differently at the health care facilities and have a significant effect on the device's validated number use lives (which in part is determined by the electrical safety testing performed on end of use life devices). This information should also be used to help develop your incoming device inspection criteria.

Performance Testing

The following deficiencies refer to the general performance testing that you have conducted to validate your remanufacturing process.

40. In Attachment E of Supplement 2, you state, "OEM-equivalent specifications have been derived from published OEM product information, in-house 'reverse engineering' activities, and the relevant requirements of applicable consensus standards." Since it does not seem possible to identify exact device specifications using these methods, please perform side-by-side comparative testing with the subject device and the matching OEM device model, and use a statistical comparison between the two devices to evaluate substantial equivalence. Please provide a copy of the full side-by-side performance testing report with your response.
41. In Module J of your original submission, you state that simulated use exercises were performed on the devices, and that each "exercise" was performed 72 times per simulated use cycle. You further state that the number 72 was derived from a survey of current users of the da Vinci system, including urologic, gynecologic, and thoracic surgeons. 60 was determined to be the high end number of manipulations/activations for any given function and a 20% safety margin (i.e., 12) was added to ensure each function would be exercised significantly more than would be expected in the field. Please provide a copy of the survey protocol and report, including the methods and full results for FDA review.
42. In Module J of your original submission, you provide protocols for the simulated use and reprocessing cycles that were performed on the device prior to each performance test. You state that "...each use cycle consisted of ultrasonic cleaning and steam sterilization according to OEM parameters..."
- a. From review of the protocols, it does not appear that defined or worst case parameters were used for the device remanufacturing or reprocessing performed on the test samples. For example, the steam sterilization parameters are listed as a temperature range, minimum exposure time, and minimum pressure, rather than discrete values. The ultrasonic cleaner temperature is also listed as a range. It is not clear why "OEM parameters" were followed rather than your own "worst case" parameters. All process tolerances for your own remanufacturing and reprocessing procedures should be defined, and treatment of the test devices should be based on the worst case tolerances (not the OEM parameters). FDA

recommends that worst case conditions in this case include longest exposure times, highest exposure temperatures, highest chemical concentrations, and shortest rinse durations; note that these worst case conditions are different than what would be expected for worst case conditions used for preparing test samples for cleaning validation studies. Please revise your protocol to have defined worst case parameters for the remanufacturing and reprocessing procedures, and provide results from a new study performed following this revised protocol.

- b. Although you provide a rationale for selecting the types of devices used for performance testing, your performance testing protocol does not explain how the individual test samples were selected for the study. Please revise your protocol to explain how the test samples were selected for the study, including their clinical use and reprocessing by the end user. This information is requested since changes in the OEM's reprocessing instructions could be implemented differently at the health care facilities and have a significant effect on the device's validated number use lives. This information should also be used to help develop your incoming device inspection criteria.
- c. It is stated on page 42 of Module J that two deviations occurred during the performance testing following your protocol. Sterilization was performed by gravity displacement rather than pre-vacuum steam sterilization method, and the ultrasonic cleaner was maintained between 45-50°C.
 - i. It is not entirely clear what deviation occurred regarding the ultrasonic cleaner (it is presumed that the temperature was maintained incorrectly, but it is not explicitly stated what the temperature was intended by the protocol). Please revise your protocol to provide a comprehensive description of the ultrasonic cleaner procedure and its effect on the results of the study, with the consideration that the conditions used in the study should be "worst case." If "worst case" conditions were not used, please repeat the study using all "worst case" conditions.
 - ii. You justify the deviation that resulted in the use of a different sterilization method (i.e., gravity displacement rather than pre-vacuum steam sterilization) by stating that the device is not shipped sterile and the only need at Rebotix is for decontaminating units upon arrival. You also discuss the fact that less steam may penetrate the flush tube inside the shaft with the gravity displacement compared to pre-vacuum. Consequently, you repeated the flush tube testing with pre-vacuum steam sterilization; however, all other testing was performed after gravity displacement steam sterilization. You further state that this deviation "...is only an issue if Rebotix was claiming sterility after being subjected to the life testing." However, FDA does not agree with this conclusion. Please note that it is your responsibility to validate not only the remanufacturing and reprocessing performed at your facility, but also the reprocessing instructions provided to the end user. Part of this validation

includes validating the number of use lives stated in the labeling if the user is to follow the provided reprocessing instructions. Therefore, it does not appear that the number of use lives has been properly validated, since the steam sterilization method used in your protocols is not what is used in your own remanufacturing procedures or what is recommended in your labeling. Please repeat all use life testing using defined, worst case parameters for the sterilization method that will be used in your remanufacturing procedures and in your reprocessing instructions for users.

- d. Section 9.10 of your performance test reports states, "On the 11th cycle step 4 of 9.8 will not utilize a Steam Autoclave cycle." However, there is no step 4 related to sterilization in Section 9.8 of the test reports, and it is not clear why the protocol will not include sterilization during that step. Please revise your reports to clearly explain the referenced statement.
43. In Module B, Device Description, you state that the remanufactured device shall harvest the original DS2505 memory device for use on the interceptor printed circuit board (PCB) assembly, Rebotix P/N PR1110-002. It is not clear if there are acceptance criteria to determine if the DS2050 memory device can be reused. Please describe your acceptance criteria for determining if the DS2050 memory device can be reused.
44. In Module J, Performance Data, Attachment J-1, the Monopolar Curved Scissors Cuts Test procedure describes cutting on chicken breast. However, in Supplement 2 Attachment C, PR3037 and PR3038, the Cutting Efficiency Test states that scissors are subjected to a cut test using TheraBand (simulated tissue) per DIN 58298. Please provide justification for this deviation from your SOP for the cutting performance tests. Please provide data to show that the use of chicken breast represents the worst case challenge for the Monopolar Curved Scissors. Furthermore, please provide a copy of the methods used in DIN 58298 so that we may fully understand your cutting protocol.
45. In Module J, Performance Data, Attachment J-1, Monopolar Curved Scissors Simulated Life testing appears to have been conducted without the use of the tip cover accessory. It is our understanding that in clinical practice, the Monopolar Curved Scissors must be used with the tip cover accessory. Please repeat the simulated life testing for the Monopolar Curved Scissors with a tip cover accessory in place, and provide the verification report.
46. In Module J, Performance Data, Attachment J-4, 13 Permanent Cautery Spatula (420184) and 5 Permanent Cautery Hook (420183) were used in simulated life testing. A total of 18 samples were tested to provide the level of statistical significance at 85% confidence of 90% reliability. However, this is a departure from the other simulated life testing, where a total of 22 samples were tested to provide the level of statistical significance at 90% confidence of 90% reliability. Please provide your justification for this departure (i.e., for using 18 samples instead of 22, and for accepting a lower level of statistical significance at 85%) for the Permanent Cautery Spatula and Permanent Cautery Hook.

47. In Module J, Performance Data, Attachment J-7, Life Testing Worst Case Analysis, you describe your use of 3 criteria in guiding the selection of 6 representative models for Rebotix Life Testing. When we reviewed the number of malfunction reports in FDA's Medical Device Reporting (MDR) Database, the Mega Suturecut Needle Driver was among the top 5 EndoWrist Instruments with the greatest number of malfunctions. Furthermore, it appears that your current Life Testing does not include an evaluation of suturing performance. Therefore, we recommend that you perform additional simulated life testing using the Mega SutureCut Needle Driver (420309). Please include an evaluation of suturing performance as part of this testing, and provide the verification report for Simulated Life Testing for the Mega SutureCut Needle Driver in your response.
48. In Module J, Performance Data, it is not clear how the RF activations parameters of Power Setting and Duration for energized instruments were selected in the RF Activation (9.7) and Post Testing/Inspection (9.11) procedures. Please provide a rationale to demonstrate that these RF Activation parameters represent worst case conditions for the simulated uses.
49. In Module J, Performance Data, it is not clear if jaw alignments are checked for graspers, forceps, needle drivers, and scissors during Post Testing/Inspection (9.11). We believe jaw alignments are critical performance characteristics for these instruments and should be evaluated following simulated life testing to verify that the jaw mechanism can withstand all additional remanufacturing, reprocessing, and reuse cycles. Please address the following issues:
- a. Please incorporate a jaw alignment inspection step during Post Testing/Inspection (After 11 Simulated Uses) for graspers, forceps, needle drivers, and scissors.
 - b. Please provide objective acceptance criteria for jaw alignment inspection. A subjective criterion, such as "The jaw must be correctly aligned" in SOP PR3024, is not adequate.
 - c. Please repeat the simulated life testing for the Monopolar Curved Scissors, the Fenestrated Bipolar Forceps, and the Mega SutureCut Needle Driver, and provide the full verification reports in your response.
50. In Attachment J-9 of Module J, you perform shipping validation on the subject device in accordance with ISTA 6 FED EX, "FedEx Procedures for Testing Packaged Products weighing up to 150 lbs." You further state, "Since three samples are required, 3 different models will be tested; the Monopolar, Bipolar and PK models, all of which are energized."

However, ISTA 6 FED EX is not an FDA-recognized standard. Furthermore, a sample size of $n = 3$ devices does not appear to be statistically justifiable. Please perform packaging validation on a statistically justifiable number of samples. We recommend the use of FDA-recognized consensus standards for this validation testing. (A current list of these standards is available at

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>). We have found that the FDA-recognized standard, ASTM D4169-09, “Standard Practice for Performance Testing of Shipping Containers and Systems,” includes distribution cycles that provide sufficient rigor for a variety of shipping and handling situations. In addition, we have accepted successful test data from packages subjected to Distribution Cycle 13 with testing at Assurance Level 1, as we believe this to be sufficiently rigorous.

51. You provide the IFU for the subject device through email on May 22, 2015. On page 3 of this IFU, Table 1-1 provides a list of environmental conditions for the subject device. This table specifies the temperature and humidity ranges for operating, storage, and transport of the subject device. However, testing to support the specified temperature and humidity ranges does not appear to be provided in the submission. Please provide a copy of the validation report to support the environmental conditions specified in the IFU. Alternatively, please remove this information from the subject IFU.

EXHIBIT 5
to
DECLARATION OF ANDREW LAZEROW IN SUPPORT OF
INTUITIVE SURGICAL INC.'S OPPOSITION TO SIS'S
MOTION IN LIMINE #5

EXHIBIT 6
to
DECLARATION OF ANDREW LAZEROW IN SUPPORT OF
INTUITIVE SURGICAL INC.'S OPPOSITION TO SIS'S
MOTION IN LIMINE #5



November 15, 2022

Iconocare Health
Rick Ferreira
President
7825 East Redfield Rd.
Suite 103
Scottsdale, Arizona 85260

Re: K210478
Trade/Device Name: 8mm Monopolar Curved Scissors
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NAY

Dear Rick Ferreira:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated September 30, 2022. Specifically, FDA is updating this SE Letter as an administrative correction. The original SE letter did not include the 510(k) summary enclosure.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Mark Trumbore, OHT4: Office of Surgical and Infection Control Devices, 301-796-5436, Mark.Trumbore@fda.hhs.gov.

Sincerely,

Mark
Trumbore -S

Digitally signed by
Mark Trumbore -S
Date: 2022.11.15
14:15:23 -05'00'

Mark Trumbore
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health



September 30, 2022

Iconocare Health
Rick Ferreira
President
7825 East Redfield Rd.
Suite 103
Scottsdale, Arizona 85260

Re: K210478
Trade/Device Name: 8mm Monopolar Curved Scissors
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: QSM, NAY
Dated: March 29, 2022
Received: March 31, 2022

Dear Rick Ferreira:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark

Trumbore -S

Digitally signed by
Mark Trumbore -S
Date: 2022.09.30
16:32:31 -04'00'

Mark Trumbore
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K210478

Device Name

8mm Monopolar Curved Scissors (420179)

Indications for Use (Describe)

The EndoWrist 8mm Monopolar Curved Scissors instrument is used with the Intuitive Surgical IS3000 da Vinci Si Surgical System for cutting, cauterizing, coagulation, manipulating and blunt dissection of tissue.

The Endoscopic Instrument Control System is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, ultrasonic shears, forceps/pick-ups, needle holders, endoscopic retractors, stabilizers, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, and delivery and placement of microwave and cryogenic ablation probes and accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, transoral otolaryngology surgical procedures restricted to benign and malignant tumors classified as T1 and T2, and for benign base of tongue resection procedures, general thoracoscopic surgical procedures, and thoracoscopically assisted cardiectomy procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use (except for transoral otolaryngology surgical procedures). It is intended to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

The 8mm Monopolar Scissors of this submission are for use only with the Intuitive Si System (Endoscopic Instrument Control System).

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Iconocare Health
Applicant Address	7825 East Redfield Rd. Suite 103 Scottsdale AZ 85260 US
Applicant Contact Telephone	480-467-8517
Applicant Contact	Mr. Rick Ferreira
Applicant Contact Email	rferreira@alliancehccpartners.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	8mm Monopolar Curved Scissors (420179)
Common Name	Endoscope and accessories
Classification Name	Endoscope and Accessories
Regulation Number	21 CFR §876.1500
Product Code	QSM, NAY

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K180033	8mm Monopolar Curved Scissors	NAY
K050369	Intuitive Surgical da Vinci Surgical System and Endowrist Instruments	NAY
K081137	Intuitive Surgical da Vinci Si Surgical System	NAY
K123329	Intuitive Surgical® da Vinci®, da Vinci S® and da Vinci Si® Surgical Systems	NAY
K170644	Da Vinci S/Si EndoWrist Instruments And Accessories	NAY

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The 8mm Monopolar Curved Scissors Instrument is used with the Intuitive Surgical IS3000 da Vinci Si Surgical System for cutting, cauterizing, coagulation, manipulating and blunt dissection of tissue. The instrument consists of the housing, shaft, wrist, and tip. The shaft and wrist allow for different axes of rotation, and the instrument tip is used to interact with the patient tissue. This instrument is reusable and is provided non-sterile.

8mm Monopolar Curved Scissor Instruments are designed to provide surgeons with natural dexterity and a greater range of motion than even the human hand. This allows for greater precision when operating in a minimally invasive environment. EndoWrist 8mm Monopolar Curved Scissor Instruments, when used with the IS3000 system, are designed to support rapid and precise suturing, dissection and tissue manipulation in surgical procedures.

Summary of Technological Characteristics:

The design, materials, and intended use of the 8mm Monopolar Curved Scissor Instruments, after an additional ten (10) reuse cycles are equivalent to the predicate device. The mechanism of action of the subject device is identical to the predicate device in that the same

standard mechanical design, materials, and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, or method of operation. The change in device specifications is to extend the useful life of the 8mm Monopolar Curved Scissor Instruments.

Performance Data:

In accordance with the Design Control process, risk analysis was conducted to evaluate the impact of modifications to the predicate device. Design verification and design validation testing were conducted on the subject device to confirm that the design outputs meet design input requirements and that the device is safe and effective for its intended use. This included the following tests:

- Biocompatibility
- Validation of Reprocessing
- Functional Performance Testing
- Electrical Safety Testing

The performance testing demonstrates that reprocessed devices are as safe and effective as the predicate and operate as originally intended.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The EndoWrist 8mm Monopolar Curved Scissors instrument is used with the Intuitive Surgical IS3000 da Vinci Si Surgical System for cutting, cauterizing, coagulation, manipulating and blunt dissection of tissue.

The Endoscopic Instrument Control System is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, ultrasonic shears, forceps/pick-ups, needle holders, endoscopic retractors, stabilizers, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, and delivery and placement of microwave and cryogenic ablation probes and accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, transoral otolaryngology surgical procedures restricted to benign and malignant tumors classified as T1 and T2, and for benign base of tongue resection procedures, general thoracoscopic surgical procedures, and thoracoscopically assisted cardiectomy procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use (except for transoral otolaryngology surgical procedures). It is intended to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

The 8mm Monopolar Scissors of this submission are for use only with the Intuitive Si System (Endoscopic Instrument Control System).

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The indications for use are the same as the predicate device.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The design, materials, and intended use of the 8mm Monopolar Curved Scissors Instruments, after an additional ten (10) reuse cycles are equivalent to the predicate device. The mechanism of action of the reusable device is identical to the predicate device in that the same standard mechanical design, materials, and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. Each individual device is tested for appropriate function of its components prior to packaging and labeling operations.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

In accordance with the Design Control process, risk analysis was conducted to evaluate the impact of modifications to the predicate device. Design verification and design validation testing were conducted on the subject device to confirm that the design outputs meet design input requirements and that the device is safe and effective for its intended use. This included the following tests:

- Biocompatibility
- Validation of Reprocessing
- Functional Performance Testing
- Electrical Safety Testing

The performance testing demonstrates that reprocessed devices are as safe and effective as the predicate and operate as originally intended.

EXHIBIT 7
to
DECLARATION OF ANDREW LAZEROW IN SUPPORT OF
INTUITIVE SURGICAL INC.'S OPPOSITION TO SIS'S
MOTION IN LIMINE #5

From: Glenn P
Sent: Wednesday, May 25, 2022 3:56 PM PDT
To: Skodacek, Ken; Chris G
Subject: Re: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Ken.

Thanks for the follow-up. Chris and I are available after 10:00 AM tomorrow. We'd be happy to speak with you, just send an invite.

Glenn

Glenn Papit

Vice President

Rebotix Repair

407-810-4176

<https://www.rebotixrepair.com>

From: Skodacek, Ken <Ken.Skodacek@fda.hhs.gov>

Sent: Wednesday, May 25, 2022 3:44 PM

To: Chris G <chris@rebotixrepair.com>; Glenn P <glennpapit@rebotixrepair.com>

Cc: CDRH Ombudsman <CDRHombudsman@fda.hhs.gov>

Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Chris and Glenn – As you requested, I discussed your proposed plan with some members of the FDA team. Could we have a brief conversation tomorrow, Thursday? What is your availability? I would like to review and confirm the next steps before sharing the plan with a larger group.

Regards,

Ken

Ken Skodacek (he/him)

CDRH Deputy Ombudsman



From: Skodacek, Ken

Sent: Thursday, May 19, 2022 11:27 PM

To: Chris G <chris@rebotixrepair.com>; Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>; Lee, Anthony <Anthony.Lee1@fda.hhs.gov>

Cc: Rick Lyon <rick@dovel.com>; Glenn P <glennpapit@rebotixrepair.com>; Trumbore, Mark <Mark.Trumbore@fda.hhs.gov>; CDRH Ombudsman <CDRHombudsman@fda.hhs.gov>

Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

OK, great. I sent you an invite for Monday at 9:30 AM ET. I've copied the staff from CDRH on this message, but we can meet privately, so that you're able to have a confidential discussion with me about your questions.

**Exhibit
DX 267**

Ken Skodacek (he/him)
CDRH Deputy Ombudsman



From: Chris G <chris@rebotixrepair.com>
Sent: Thursday, May 19, 2022 9:26 AM
To: Skodacek, Ken <Ken.Skodacek@fda.hhs.gov>; Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>; Lee, Anthony <Anthony.Lee1@fda.hhs.gov>
Cc: Rick Lyon <rick@dovel.com>; Glenn P <glennpait@rebotixrepair.com>; Trumbore, Mark <Mark.Trumbore@fda.hhs.gov>; CDRH Ombudsman <CDRHombudsman@fda.hhs.gov>
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Good morning Ken,
Thank you for the quick response on this matter. We can be available Monday, Thursday, or Friday next week.

Please let me know if any of these dates work for you. Thank you.

Sincerely,

Chris Gibson
Chief Operations Officer



539 Pasadena Avenue South
St. Petersburg, FL 33707
P: (727) 345-6362
F: (727) 343-4637
C: (813) 245-3974
www.rebotixrepair.com

From: Skodacek, Ken <Ken.Skodacek@fda.hhs.gov>
Sent: Wednesday, May 18, 2022 7:35 AM

To: Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>; Chris G <chris@rebotixrepair.com>; Lee, Anthony <Anthony.Lee1@fda.hhs.gov>
Cc: Rick Lyon <rick@dovel.com>; Glenn P <glennpapit@rebotixrepair.com>; Trumbore, Mark <Mark.Trumbore@fda.hhs.gov>; CDRH Ombudsman <CDRHombudsman@fda.hhs.gov>
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Thank you, Katelyn, for the introduction. **Chris** – Please let me know your availability this week to discuss any questions that you might have. Once I hear back from you, I can send you an invitation for a date/time that works for our mutual schedules.

Ken Skodacek (he/him)

CDRH Deputy Ombudsman

Center for Devices and Radiological Health

Office of Policy

U.S. Food and Drug Administration

Tel: 301-796-6364

Ken.Skodacek@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide your [feedback](#).

From: Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>

Sent: Tuesday, May 17, 2022 6:24 PM

To: Chris G <chris@rebotixrepair.com>; Lee, Anthony <Anthony.Lee1@fda.hhs.gov>

Cc: Rick Lyon <rick@dovel.com>; Glenn P <glennpapit@rebotixrepair.com>; Trumbore, Mark <Mark.Trumbore@fda.hhs.gov>; Skodacek, Ken <Ken.Skodacek@fda.hhs.gov>

Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Hi Chris,

Thanks for reaching out. To clarify about escalation, we have not taken a regulatory or enforcement action at this time for the formal appeals process to apply. As stated on the call, we do believe the activities you are performing constitute remanufacturing and require premarket review. As noted in the guidance documents listed below, this is not considered a “significant decision.” However, you are welcome to escalate the discussion and decision with the next level supervisor. In this case that would most likely be Dr. Cynthia Long, Division Director of General Surgery Devices. After Dr. Long, the next level supervisor would be Dr. Binita Ashar, Director of the Office of Surgery and Infection Control Devices.

The CDRH Deputy Ombudsman, Ken Skodacek, was on our last call and is familiar with the situation. He would be happy to answer any additional questions you may have on the process. Additionally, these two guidance documents are related to appeals; I encourage you to review them if you have not already.

1. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes>
2. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes-questions-and-answers-about-517a>.

I hope this answers your questions. Thanks again for reaching out.

-Katelyn

Katelyn R. Bittleman, Ph.D. (she/her/hers)

Policy Analyst, Compliance and Quality Staff

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4250 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (240) 402-1478

Katelyn.Bittleman@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: [CDRH Customer Satisfaction Survey](#)

From: Chris G <chris@rebotixrepair.com>

Sent: Tuesday, May 17, 2022 11:16 AM

To: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>

Cc: Rick Lyon <rick@dovel.com>; Glenn P <glennpapat@rebotixrepair.com>; Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>; Trumbore, Mark <Mark.Trumbore@fda.hhs.gov>

Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Dr. Lee and FDA Team:

Thank you for taking the time to speak with us. We certainly want to continue working with the FDA to resolve this matter, but we were hoping you could clarify something for us. Based on your emails of April 6th and 8th and zoom meeting of April 8th, we understood that the FDA had made a "decision" classifying Rebotix activities as remanufacture. We further understood that we had the right to appeal this decision for supervisory review under 21 CFR 10.75. During the May 11th zoom, someone (Dr. Bittleman I believe) specifically referenced supervisory review under 21 CFR 10.75 as an option. But then later during the May 11th zoom, someone else (Dr. Trombore I believe) stated that "no formal decision had been made" and there was "nothing for [us] to appeal" at this point. We are a bit confused by this apparent contradiction and how it affects next steps. Can you please clarify. When you indicate below that we have the option to "escalate to a higher level for additional discussion," are you referring to supervisory review under 21 CFR 10.75 or some other process? Also, at some point, would it be acceptable for Rebotix to reach out to the FDA Ombudsman?

Thank you again for your time.

Sincerely,

Chris Gibson

Chief Operations Officer



539 Pasadena Avenue South

St. Petersburg, FL 33707

P: (727) 345-6362

F: (727) 343-4637

C: (813) 245-3974

www.rebotixrepair.com

From: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>

Sent: Friday, May 13, 2022 2:59 PM

To: Chris G <chris@rebotixrepair.com>

Cc: Rick Lyon <rick@dovel.com>; Glenn P <glennpapit@rebotixrepair.com>

Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Dear Mr. Gibson and Rebotix team,

Thank you again for having the call with us on Wednesday. From our understanding, you will let me know how you intend to proceed within the next two weeks. Those options being:

1. Requesting to escalate to a higher level for additional discussion,
2. Committing to a premarket submission, or
3. Stating that you will no longer be marketing this activity.

In addition, it was suggested that other firms are engaged in this space without the same level and breadth of quality checks and testing that your team uses. If you can share additional information about those companies, we would very much be interested in learning about them. I look forward to hearing back from you.

Best regards,

Anthony Lee

Anthony Lee, PhD, MBA

Team Lead

Robotic Assisted Surgery Devices Team

Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices

Office of Product Evaluation and Quality | Center for Devices and Radiological Health



Office: (240) 402-5935

E-mail: Anthony.Lee1@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?ID=1611&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

From: Lee, Anthony

Sent: Thursday, May 5, 2022 4:39 PM

To: Chris G <chris@rebotixrepair.com>; Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>

Cc: Rick Lyon <rick@dovel.com>; Glenn P <glennpapat@rebotixrepair.com>

Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Hi Mr. Gibson,

We have availability next week as follows:

Wednesday, 5/11 at 4PM EDT

Thursday, 5/12 at 4:30PM EDT

If neither of these work, please let me know and we will check additional options for Friday and beyond.

Regarding your question, I don't have an immediate answer to that, but we will be able to discuss any process questions you may have during the meeting.

Thank you,
Anthony Lee

Anthony Lee, PhD, MBA

Team Lead

Robotic Assisted Surgery Devices Team

Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices

Office of Product Evaluation and Quality | Center for Devices and Radiological Health





Office: (240) 402-5935

E-mail: Anthony.Lee1@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?ID=1611&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

From: Chris G <chris@rebotixrepair.com>

Sent: Thursday, May 5, 2022 9:13 AM

To: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>; Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>

Cc: Rick Lyon <rick@dovel.com>; Glenn P <glennpapit@rebotixrepair.com>

Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Dr. Lee,

We are available next Tuesday, Wednesday or Thursday as you request. Please send potential times available for you and your team to attend the Zoom call. Also, we assume that the date to file an appeal will be extended due to your requested delay. Please confirm. Thank you.

Sincerely,

Chris Gibson

Chief Operations Officer



539 Pasadena Avenue South

St. Petersburg, FL 33707

P: (727) 345-6362

F: (727) 343-4637

C: (813) 245-3974

www.rebotixrepair.com

From: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>
Sent: Wednesday, May 4, 2022 5:11 PM
To: Chris G <chris@rebotixrepair.com>; Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>
Cc: Rick Lyon <rick@dovel.com>; Glenn P <glennpapi@rebotixrepair.com>
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Dear Mr. Gibson,
Apologies for causing a delay, but we have run into a scheduling conflict for this Friday's time slot and need to reschedule the call. It would only be a few days, as we are trying our best to honor your request for a meeting as soon as possible. We are currently trying to find availability on next Tuesday, Wednesday, or Thursday. I will follow up with potential times as soon as I hear back on availability, but please let me know if those dates are already not workable for your team.

Thank you,
Anthony Lee

Anthony Lee, PhD, MBA
Team Lead

Robotic Assisted Surgery Devices Team
Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices
Office of Product Evaluation and Quality | Center for Devices and Radiological Health



Office: (240) 402-5935
E-mail: Anthony.Lee1@fda.hhs.gov
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
<https://www.research.net/s/cdrhcustomerservice?ID=1611&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

From: Chris G <chris@rebotixrepair.com>
Sent: Monday, May 2, 2022 2:31 PM
To: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>; Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>

Cc: Rick Lyon <rick@dovel.com>; Glenn P <glennpapit@rebotixrepair.com>

Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Thank you.

From: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>

Sent: Monday, May 2, 2022 2:29 PM

To: Chris G <chris@rebotixrepair.com>; Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>

Cc: Rick Lyon <rick@dovel.com>; Glenn P <glennpapit@rebotixrepair.com>

Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Dear Mr. Gibson,

Yes, the date and time are confirmed on our end (this Friday at 10AM Eastern). I will send over the meeting invitation soon.

Thank you,

Anthony Lee, PhD, MBA

Team Lead

Robotic Assisted Surgery Devices Team

Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices

Office of Product Evaluation and Quality | Center for Devices and Radiological Health



Office: (240) 402-5935

E-mail: Anthony.Lee1@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?ID=1611&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

From: Chris G <chris@rebotixrepair.com>

Sent: Monday, May 2, 2022 2:26 PM

To: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>; Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>

Cc: Rick Lyon <rick@dovel.com>; Glenn P <glennpapit@rebotixrepair.com>

Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Dr. Lee,
Will you please confirm this zoom call? Thank you.

Sincerely,

Chris Gibson

Chief Operations Officer



539 Pasadena Avenue South

St. Petersburg, FL 33707

P: (727) 345-6362

F: (727) 343-4637

C: (813) 245-3974

www.rebotixrepair.com

From: Chris G

Sent: Thursday, April 28, 2022 1:35 PM

To: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>; Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>

Cc: Rick Lyon <rick@dovel.com>; Glenn P <glennpapit@rebotixrepair.com>

Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Dear Dr. Lee,
Friday May 6th, at 10 am EDT is perfect for us. Please send us the zoom call invite. Thank you.

Sincerely,

Chris Gibson

Chief Operations Officer



539 Pasadena Avenue South
St. Petersburg, FL 33707
P: (727) 345-6362
F: (727) 343-4637
C: (813) 245-3974
www.rebotixrepair.com

From: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>
Sent: Thursday, April 28, 2022 12:58 PM
To: Chris G <chris@rebotixrepair.com>; Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>
Cc: Rick Lyon <rick@dovel.com>; Glenn P <glennpapit@rebotixrepair.com>
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Dear Mr. Gibson,
May 2 and 3 conflict with our schedules. I would like to propose any of the following alternatives:

Thursday May 5: 11AM or 3PM EDT
Friday May 6: 10AM EDT

If none of these times work, please let me know.

Thank you,
Anthony

Anthony Lee, PhD, MBA
Team Lead

Robotic Assisted Surgery Devices Team
Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices
Office of Product Evaluation and Quality | Center for Devices and Radiological Health



Office: (240) 402-5935
E-mail: Anthony.Lee1@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?ID=1611&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

From: Chris G <chris@rebotixrepair.com>

Sent: Monday, April 25, 2022 12:36 PM

To: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>; Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>

Cc: Rick Lyon <rick@dovel.com>; Glenn P <glennpapit@rebotixrepair.com>

Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Dr. Lee & Dr. Bittleman.

We are a 3rd party service provider consistent with the FDA's definition, and all of our repair business aligns with such. We service instruments in continuous hospital ownership and do not affect the effectiveness or the intended use of these instruments.

During our Zoom call you mentioned that our service was a "complicated" and "murky area" for FDA oversight, yet we have been more than open about our service process. On Feb. 28, 2020 the FDA reached out to us regarding our process. We immediately cooperated by providing all requested information via a succession of informative emails. We provided ample evidence of proper due diligence (formal risk management and design under 13485; service process performed under 9001; hospital/customer due diligence), and that our process returns the instrument to its safe operating condition.

In June of 2019 Dr. Bittleman visited our booth at the AAMI show in Cleveland at which time she was able to examine all aspects of our repair process, and ask any pertinent questions. She expressed no safety or other issues that would concern the FDA during that meeting.

Since the FDA's original contact we heard nothing back from the FDA for a year and nine months, which from our understanding, would indicate that the FDA was satisfied with our responses and the matter was closed. Despite the fact there has been no change in our process, or any known safety issues or customer complaints, on Nov. 16, 2021 we received an overnight delivery indicating the FDA was reopening the investigation. Then on April 8, 2022 we were advised of the FDA's determination that our process constituted remanufacturing.

If, as being suggested, there is an actual issue of patient safety, why has the FDA waited two and a half years to seek correction? By taking this action the FDA is effectively shuttering a small business that is positively affecting the costs of surgery budgets across the country. The question is why?

Following our Zoom call we requested follow up discussion. The FDA declined, choosing instead to direct us to a Q-submission. Our understanding is that our only alternative at this point is to initiate a formal

review/appeal with the FDA. We respectfully request to discuss this matter again. Please respond and advise if you are available for a meeting or call next Monday May 2nd, or Tuesday May 3rd. Thank you.

Sincerely,

Chris Gibson

Chief Operations Officer



539 Pasadena Avenue South

St. Petersburg, FL 33707

P: (727) 345-6362

F: (727) 343-4637

C: (813) 245-3974

www.rebotixrepair.com

From: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>

Sent: Friday, April 22, 2022 12:09 PM

To: Chris G <chris@rebotixrepair.com>

Cc: Rick Lyon <rick@dovel.com>

Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Dear Mr. Gibson,

We would like to have a brief phone call to discuss the timeline and next steps. Proposed times are (all Eastern time):

4/25 at 2PM or 2:30PM

4/26 at 1:30PM or 2:30PM

If none of these times work, please let me know.

Thanks,

Anthony Lee, PhD, MBA

Team Lead

Robotic Assisted Surgery Devices Team

Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices

Office of Product Evaluation and Quality | Center for Devices and Radiological Health



Office: (240) 402-5935

E-mail: Anthony.Lee1@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?ID=1611&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

From: Lee, Anthony

Sent: Tuesday, April 19, 2022 4:09 PM

To: Chris G <chris@rebotixrepair.com>

Cc: Rick Lyon <rick@dovel.com>; Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>

Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Dear Mr. Gibson,

Management has requested that you submit a Q-submission as previously described. This will allow your company to have a full documentation of items that were reviewed along with an official FDA written response, teleconference (if desired), and meeting minutes (if applicable). Please let me know if you have any questions about the process.

Thank you,
Anthony Lee

Anthony Lee, PhD, MBA

Team Lead

Robotic Assisted Surgery Devices Team

Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices

Office of Product Evaluation and Quality | Center for Devices and Radiological Health



Office: (240) 402-5935

E-mail: Anthony.Lee1@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?ID=1611&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

From: Chris G <chris@rebotixrepair.com>

Sent: Friday, April 15, 2022 3:13 PM

To: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>

Cc: Rick Lyon <rick@dovel.com>; Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>

Subject: Re: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dr. Lee,

Thank you for the quick response, we would very much appreciate a meeting the week of 4/25. Thank you.

Sincerely,

Chris Gibson

On Apr 15, 2022, at 2:55 PM, Lee, Anthony <Anthony.Lee1@fda.hhs.gov> wrote:

Sending a quick followup. I'm checking with management to see if we can fast-track a meeting with your proposed week. If that won't work, then the previously-mentioned Q-submission will be the proper approach. I'll send another followup on Monday to confirm.

Thanks,
Anthony

Anthony Lee, PhD, MBA

Team Lead

Robotic Assisted Surgery Devices Team

Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices

Office of Product Evaluation and Quality | Center for Devices and Radiological Health



Office: (240) 402-5935

E-mail: Anthony.Lee1@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?ID=1611&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

From: Lee, Anthony

Sent: Friday, April 15, 2022 10:34 AM

To: Chris G <chris@rebotixrepair.com>; Rick Lyon <rick@dovel.com>

Cc: Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>

Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Mr. Gibson,

Thank you for following up. I was on leave until yesterday and have been catching up with my messages. We are open to additional discussion, however this should occur through the formal [Q-submission process](#). With your submission, you can provide information for the FDA team to review along with any questions in which you would like a formal response.

If you wish to proceed with a Q-submission, please confirm and we will stand by for your submission. Due to the ongoing pandemic, FDA is not currently open to in-person meetings, however teleconferences are still acceptable.

Thanks,
Anthony

Anthony Lee, PhD, MBA

Team Lead

Robotic Assisted Surgery Devices Team

Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices

Office of Product Evaluation and Quality | Center for Devices and Radiological Health



Office: (240) 402-5935

E-mail: Anthony.Lee1@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?ID=1611&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to

deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

From: Chris G <chris@rebotixrepair.com>
Sent: Friday, April 15, 2022 9:16 AM
To: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>; Rick Lyon <rick@dovel.com>
Cc: Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>
Subject: Re: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dr. Lee and Dr. Bittleman,
We are requesting confirmation that you have received our email dated 4/11 and that we have requested an in-person meeting for the week of 4/25. Please confirm, thank you.

Sincerely,

Chris Gibson

On Apr 11, 2022, at 11:14 AM, Chris G <chris@rebotixrepair.com> wrote:

Dear Dr. Lee and Dr. Bittleman,

Thank you for your time and consideration. We appreciate your acknowledgment on the call that whether a process constitutes remanufacturing is a "murky area" under the current FDA guidelines and that new guidelines are forthcoming. We also appreciate your explanation of our options going forward: whether to pursue FDA clearance (e.g., a 510(k)) or to provide Objections to your decision so that the FDA can further consider the issue as it works to finalize its guidelines. To this end we wish to request an in person meeting at your offices to begin the collaborative assistance you offered on our zoom call. Please let us know if you have availability the week of April 25th.

Best regards,

Chris Gibson

From: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>
Sent: Friday, April 8, 2022 2:28 PM
To: Rick Lyon <rick@dovel.com>; Chris G <chris@rebotixrepair.com>

Cc: Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>

Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Dear Rick and Chris,

Thank you for your time earlier today. As mentioned during our call, the Agency believes that the activities of Rebotix constitute remanufacturing and would require FDA review and clearance (e.g. 510(k) / de Novo). We therefore request that Rebotix stop engaging in the current activities until an application is reviewed and cleared/granted.

The instruments in question no longer maintain the same safety and effectiveness profile as cleared with the original manufacturer's own submission. During premarket review, FDA reviews test data to the labeled number of reuse cycles. This includes, but is not limited to, items such as electrical safety, reprocessing, software, and general performance testing. By extending the number of uses and modifying the instrument with a new chip, the prior information is no longer valid and requires additional review to the new labeled usage limit in order to establish safety and effectiveness. This is therefore different than returning the device to its original condition.

Please let us know if you have any further questions and what your intentions are for next steps.

Thank you again,
Anthony

Anthony Lee, PhD, MBA

Team Lead

Robotic Assisted Surgery Devices Team

Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices

Office of Product Evaluation and Quality | Center for Devices and Radiological Health



Office: (240) 402-5935

E-mail: Anthony.Lee1@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?ID=1611&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

From: Rick Lyon <rick@dovel.com>

Sent: Wednesday, April 6, 2022 1:13 PM

To: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>

REBOTIX175727

Cc: Chris G <chris@rebotixrepair.com>

Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Thank you, Anthony. 1 PM ET works for us. What is the best number to reach you? Or if you prefer, I can send call-in information.

Thanks,
Rick

From: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>

Sent: Wednesday, April 06, 2022 5:58 AM

To: Rick Lyon <rick@dovel.com>

Cc: Chris G <chris@rebotixrepair.com>

Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Dear Rick,

A decision has been made regarding CPT2000126 and Rebotix Repair. We would like to request a short teleconference. Are you and someone from Rebotix available to discuss this Friday at 1PM ET?

Thanks,
Anthony

Anthony Lee, PhD, MBA

Team Lead

Robotic Assisted Surgery Devices Team

Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices

Office of Product Evaluation and Quality | Center for Devices and Radiological Health



Office: (240) 402-5935

E-mail: Anthony.Lee1@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?ID=1611&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

From: Lee, Anthony
Sent: Monday, December 13, 2021 10:56 AM
To: Rick Lyon <rick@dovel.com>
Cc: Chris G <chris@rebotixrepair.com>
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Good morning Rick,
We have discussed your request internally, and we are ok with extending the response by an additional 30 days. We look forward to hearing back from you in January.

Regards,
Anthony

Anthony Lee, PhD, MBA
Team Lead

Robotic Assisted Surgery Devices Team
Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices
Office of Product Evaluation and Quality | Center for Devices and Radiological Health



Office: (240) 402-5935
E-mail: Anthony.Lee1@fda.hhs.gov
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
<https://www.research.net/s/cdrhcustomerservice?ID=1611&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

From: Rick Lyon <rick@dovel.com>
Sent: Friday, December 10, 2021 11:51 AM
To: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>
Cc: Chris G <chris@rebotixrepair.com>
Subject: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Dr. Lee,

Thank you for taking the time to speak with me. Following up on our conversation, would it be possible to extend the deadline for our submission of the information you requested by 30 days? This would make the information due January 15, 2022, instead of next Thursday (December 16, 2021).

Best regards,
Rick Lyon
310-656-7066
Counsel for Rebotix Repair LLC

EXHIBIT 8
to
DECLARATION OF ANDREW LAZEROW IN SUPPORT OF
INTUITIVE SURGICAL INC.'S OPPOSITION TO SIS'S
MOTION IN LIMINE #5

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

SURGICAL INSTRUMENT SERVICE)
COMPANY, INC.,)
)
Plaintiff,)
)
vs.) Case No.
) 3:21-CV-03496-VC
INTUITIVE SURGICAL, INC.,)
)
Defendant.)
-----)

VIRTUAL VIDEOCONFERENCE VIDEO-RECORDED
DEPOSITION OF GREG POSDAL, 30(B)(1)

Tuesday, November 1, 2022
Remotely Testifying from Phoenix, Arizona

Stenographically Reported By:
Hanna Kim, CLR, CSR No. 13083
Job No. 5541334-B

1 approved as part of that clearance?

2 A. It's my understanding that they approved
3 of the process of resetting the chip and going
4 through the testing and evaluation process.

5 Q. How many times did the FDA approve Restore 13:19:14
6 or its affiliate to perform the reset?

7 MR. SNYDER: Objection to form.

8 THE WITNESS: I would have no way of
9 knowing that.

10 BY MR. CHAPUT: 13:19:28

11 Q. Do you know if there's a -- a limit on the
12 number of times that the reset can be performed
13 under that clearance?

14 MR. SNYDER: Objection.

15 THE WITNESS: At this time, I do not. 13:19:36

16 BY MR. CHAPUT:

17 Q. Do you know if there's a limit on the
18 number of uses that can be added to the EndoWrist
19 under the 510(k) clearance?

20 MR. SNYDER: Objection. 13:19:48

21 THE WITNESS: I do not.

22 BY MR. CHAPUT:

23 Q. Are you aware that Rebotix applied for
24 510(k) clearance for its EndoWrist reset process
25 back in 2014? 13:20:06

1 MR. McCAULLEY: Object to form.

2 THE WITNESS: I would assume that that was
3 discussed. I don't recall those discussions.

4 BY MR. CHAPUT:

5 Q. Do you know the outcome of Rebotix's 13:20:18
6 510(k) application for its EndoWrist reset process?

7 A. I do not.

8 Q. So you don't know whether the FDA found
9 deficiencies in Rebotix's application?

10 A. I -- I don't. There were -- I think there 13:20:42
11 were conversations with Chris Gibson that he didn't
12 understand what the hold up was and why they weren't
13 approving it that they got a letter that wasn't an
14 official type letter from the FDA as a -- as a
15 rejection or approval. It -- it seemed to be an 13:21:14
16 opinion. It didn't follow the -- what he said was
17 the normal process for moving these through the
18 process. I -- and -- and the exact specifications,
19 I don't know.

20 Q. This -- this letter that you're referring 13:21:33
21 to that Chris Gibson said he received, when -- when
22 did that happen?

23 A. I don't know.

24 Q. Is that something that -- that happened
25 within the last year? 13:21:46

Page 55

EXHIBIT 9
to
DECLARATION OF ANDREW LAZEROW IN SUPPORT OF
INTUITIVE SURGICAL INC.'S OPPOSITION TO SIS'S
MOTION IN LIMINE #5

*** CONFIDENTIAL ATTORNEYS EYES ONLY ***

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

SURGICAL INSTRUMENT SERVICE)
COMPANY, INC.,) Case No.:
) 3:21-cv-03496-VC
Plaintiff,)
) Lead Case No.:
vs.) 3:21-cv-03825-VC
)
INTUITIVE SURGICAL, INC.,)
)
Defendant)
)
IN RE: DA VINCI SURGICAL ROBOT)
ANTITRUST LITIGATION)
)
THIS DOCUMENT RELATES TO:)
ALL ACTIONS)
)

*** CONFIDENTIAL ATTORNEYS EYES ONLY ***

30(b)(6) DEPOSITION OF:

KEITH ROBERT JOHNSON

THURSDAY, OCTOBER 27, 2022

9:06 a.m. Mountain Standard Time

REPORTED BY:
Vickie Blair
CSR No. 8940, RPR-CRR
JOB NO. 5539883
PAGES 1 - 122

Page 1

*** CONFIDENTIAL ATTORNEYS EYES ONLY ***

1 provided, we felt that it was a repair. 10:52:11

2 BY MR. CHAPUT: 10:52:16

3 Q Apart from the Posdal family's background 10:52:20

4 and the information provided by Rebotix, did SIS 10:52:27

5 perform any other analysis of whether the service it 10:52:33

6 was offering was a repair and not reprocessing? 10:52:36

7 MR. VAN HOVEN: Objection to form. 10:52:39

8 THE WITNESS: Not that I'm aware of. 10:52:48

9 BY MR. CHAPUT: 10:52:50

10 Q In 2019 when SIS entered into its 10:52:52

11 relationship with Rebotix, was it aware that a Rebotix 10:52:56

12 entity submitted a 510K application to FDA in 2014 10:52:59

13 regarding the Rebotix interceptor chip? 10:53:05

14 A I don't recall being told the specific 10:53:13

15 dates, but we were made aware of the fact that they had 10:53:16

16 filed a 510K. 10:53:21

17 Q And just to make -- to make sure I'm 10:53:23

18 clear, the interceptor chip is the trade name that 10:53:26

19 Rebotix used for the chip that it -- it places to 10:53:30

20 circumvent the use counter; is that right? 10:53:34

21 MR. VAN HOVEN: Objection to form. 10:53:37

22 THE WITNESS: I don't know that I'm 10:53:42

23 familiar with the word "interceptor," I just know that 10:53:43

24 they had filed a 510K to be able to rechip the devices. 10:53:46

25 /// ///

1 BY MR. CHAPUT: 10:53:51

2 Q Okay. At the time that SIS entered into 10:53:55

3 its relationship with Rebotix, did Rebotix tell SIS the 10:53:57

4 outcome of the 510K application? 10:54:02

5 A I don't remember ever being told any 10:54:13

6 outcomes. 10:54:14

7 Q So SIS was not aware that the FDA found 10:54:17

8 deficiencies in Rebotix's 510K application? 10:54:20

9 MR. VAN HOVEN: Objection to form. 10:54:25

10 THE WITNESS: I don't remember ever being 10:54:26

11 told that. 10:54:34

12 BY MR. CHAPUT: 10:54:34

13 Q SIS was not aware that the FDA told 10:54:34

14 Rebotix in June 2015 that it could not market its 10:54:37

15 device without 510K clearance? 10:54:40

16 MR. VAN HOVEN: Objection to form. 10:54:44

17 THE WITNESS: Speaking for myself, no, I 10:54:48

18 was not aware of that. 10:54:51

19 BY MR. CHAPUT: 10:54:53

20 Q SIS was not aware of that fact that 10:54:53

21 Rebotix withdrew its 510K application in 2015? 10:54:56

22 MR. VAN HOVEN: Objection to form. 10:55:00

23 THE WITNESS: Not that I know of. 10:55:02

24 BY MR. CHAPUT: 10:55:04

25 Q Was SIS aware that FDA told one of 10:55:11

EXHIBIT 10
to
DECLARATION OF ANDREW LAZEROW IN SUPPORT OF
INTUITIVE SURGICAL INC.'S OPPOSITION TO SIS'S
MOTION IN LIMINE #5

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

SURGICAL INSTRUMENT SERVICE)
COMPANY, INC.,)
)
Plaintiff,)
)
vs.) Case No.
) 3:21-CV-03496-VC
INTUITIVE SURGICAL, INC.,)
)
Defendant.)
-----)

VIRTUAL VIDEOCONFERENCE VIDEO-RECORDED
DEPOSITION OF GREG POSDAL
30(B)(6), SURGICAL INSTRUMENT SERVICE COMPANY

Tuesday, November 1, 2022
Remotely Testifying from Phoenix, Arizona

Stenographically Reported By:
Hanna Kim, CLR, CSR No. 13083
Job No. 5541334-A

1 A. That is correct.

2 Q. SIS did not clean EndoWrist instruments?

3 A. Correct.

4 Q. SIS did not sharpen EndoWrist instruments?

5 A. Correct. 09:54:37

6 Q. SIS did not align EndoWrist instrument
7 tips?

8 A. Correct.

9 Q. The reset process on the EndoWrist
10 instrument required opening the instrument; correct? 09:54:58

11 A. Correct.

12 Q. When opening the instrument, did SIS or
13 Rebotix have to shave down pins on the instrument?

14 A. No.

15 Q. When opening the instrument, did SIS or 09:55:14
16 Rebotix have to forcibly remove pins from the
17 instrument?

18 A. No.

19 Q. When opening the EndoWrist instrument, did
20 SIS or Rebotix have to forcibly remove screws from 09:55:22
21 the instrument?

22 A. No.

23 Q. What testing did SIS or Rebotix perform to
24 ensure that the process of opening the instrument
25 did not affect -- affect its function? 09:55:36

1 A. I can't answer that for Rebotix.

2 Q. And for SIS?

3 A. We did not perform that. I -- I can say
4 that I -- as part of the meeting with Chris Gibson,
5 they had a device that, without getting too 09:56:00
6 technical, stop me if I'm going down a path that --
7 that I shouldn't be going down. But the two halves
8 of the instrument are held together with locking
9 tabs. They're made to deflect out of position
10 and then -- and then lock into place, once the two 09:56:20
11 sides are pressed together. The device merely moved
12 those tabs as they would when they were being
13 inserted to slide them out. Nothing was damaged,
14 nothing was shaved on, nothing was removed.

15 Q. How do you know that was the process that 09:56:37
16 took place?

17 A. I believe I visually saw it while I was at
18 Rebotix' lab.

19 Q. When's the last time you saw that process
20 performed? 09:57:07

21 A. That would have been the only time.
22 When -- mid 2019.

23 Q. Have you spoken with anyone about that
24 process since?

25 A. No. 09:57:19

FILER'S ATTESTATION

I, Joshua Van Hoven, am the ECF User whose ID and password are being used to file this document. In compliance with Civil Local Rule 5-1(i)(3), I hereby attest that the signatories identified above have concurred in this filing.

Dated: November 11, 2024

McCAULLEY LAW GROUP LLC

By: /s/ Joshua Van Hoven

JOSHUA V. VAN HOVEN (CSB#262815)

E-Mail: josh@mccaulleylawgroup.com
3001 Bishop Dr., Suite 300
San Ramon, California 94583
Telephone: 925.302.5941

Attorney for SURGICAL INSTRUMENT SERVICE COMPANY, INC.